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Special Issue on Bioethics in Asia

Guest Editors: **Leonardo D. de Castro**
Ciriaco M. Sayson, Jr.

- **Bioethics in Asia: An Overview**
  Leonardo D. de Castro
- **Asian Bioethics: Theoretical Background**
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- **Genetically Modified Food Seeds: Health, Socio-economic, Environmental and Religious Aspects, An Israeli Perspective**
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- **The Moral Status of the Human Embryo in Chinese Stem Cell Research**
  Yanguang Wang
- **The Rise and Fall of Embryonic Stem Cell Research in Korea**
  SONG Sang-yong

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Special issue of Asian Biotechnology and Development Review *on Bioethics was launched by the Science and Technology Secretary of the Philippines Dr. Estrella Alabastro in Manila at the Third Asian Conference on Biotechnology and Development on 9 November 2006. RIS Adjunct Senior Fellow Dr. Edgar DaSilva presented her the special issue.*

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Secretary Estrella Alabastro addressing the gathering.

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Bioethics in Asia: An Overview

Editorial Introduction

Leonardo D. de Castro*

Advances in biotechnology provide new opportunities for development, but also new challenges to established values and traditions. In many cases, the advances give rise to dangers that need to be carefully monitored so that harm and risks could be minimized, if not entirely avoided. The harm and risks, as well as the benefits against which they need to be weighed, are a primary concern for bioethics. Bioethics thus strives to protect human beings from the dangers that are inevitably linked to scientific discovery. The process draws attention to the double-edged character of new technology and tries to find ways to achieve the benefits of development with the least harm to all concerned.

This role for bioethics is soundly illustrated in Frank Leavitt's contribution to this issue of the *Asian Biotechnology and Development Review*, entitled "Genetically modified food seeds: health, socio-economic, environmental and religious aspects, an Israeli perspective." While acknowledging that ethical problems concerning genetically modified organisms are not entirely unique, Leavitt points out that these problems are special cases involving new varieties or breeds of food crops and other organisms. Without genetic modification, these new varieties could have been the result of traditional methods of selective breeding or interbreeding, undertaken to bring about flora or fauna that is tastier, better looking, or more useful than other breeds. Some varieties may also be regarded as new only in the sense that they were only recently introduced into a specific eco-system, although they have already existed elsewhere for a long time.

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Given the cost (monetary and otherwise) involved in GM research and development, Leavitt wants us to consider how much more we could achieve if all the research funds currently devoted to fashionable GM techniques were applied to improving methods of agriculture that have stood the test of time. More importantly, he raises not only the question of cost – or the issue of balancing risks against benefits – but also the concern regarding the beneficiaries of development. He aptly reminds us that the methods of agriculture need to "serve the majority of the needy people in the world." Concerning the impact of GMOs on the environment, Leavitt gives the example of The Kitchen Garden Scheme as one of the many potential ways to improve traditional agriculture as an alternative, as he asserts that priority needs to be given to returning the mountains, jungles, deserts and forests to their traditional inhabitants.

It is not a mere coincidence that much space is given in this issue to embryonic stem cell research. Important initiatives have been taken around the world in this area and Asian laboratories have been a busy hunting ground for those in search of badly needed cures for diseases that have tormented many human beings. Whereas many European and American countries have chosen to thread slowly, Asian countries have chosen to pick up the slack in what has been perceived by some as a race against the clock, but by others as a race among scientists eager to prove their mettle against their kind.

The latter kind of race is what the world appeared to have witnessed in the case of the Korean veterinarian, Hwang Woo-suk, who initially won not only the adulation of his countrymen, but the political and financial support of his government. Having acquired an enviable reputation for cloning a dog, Hwang easily attracted support for further research. It was later discovered that this folk hero had illegally acquired eggs from women and lied about the origin of cells that his team had allegedly produced by cloning. The result has been a loss of face for the Korean government as well as for the others who had invested their faith in Hwang. Sang-yong Song reminds us that the misconduct in acquiring eggs was no less serious than the fraud committed in the cloning research and that it is vital for Koreans to restore public respect for life in order to bring closure to the issues in a decisive way. Observing that Korea has suffered from its failure to liquidate the past properly (e.g. in the case of the Japanese colonial rule, the Korean War, two military dictatorships, and the Kwangju massacre), Song argues that the Hwang scandal should be finished neatly, or Koreans can expect to face a similar experience in the future.

The Hwang experience illustrates the need to provide a structure for political-administrative responsibility and transparent decision processes. It also highlights the importance of scientific criticism and of accountability for setting up a system of mentorship that values scientific integrity. Most importantly, Song reminds fellow Koreans, we have come to rethink what science really is and where science should go. In this case, we engage in what may be labeled as "bioethics as forethought," as opposed to bioethics as mere afterthought. Quite simply, we engage in bioethics as mere afterthought when our concern is limited to the harm that may follow from the use of specific biotechnology. On the other hand, we engage in bioethics as forethought when we actively examine what we seek to achieve with scientific research and development.

Yanguang Wang's article deals with the question of life in a very specific context. Reacting to the release of the "Ethical Guidelines for Research on Human Embryonic Stem Cells" in January 2004 by the Ministry of Science and Technology and the Ministry of Health in Beijing, China, she attempts a clarification of the moral status of the human embryo. She highlights Article 5 of the Guidelines, which provides that human embryonic stem cells used for research can be derived from spare gametes or blastula remaining after in vitro fertilization (IVF); fetal cells after natural or voluntarily selective abortion; blastula or monosexual split blastula by somatic cell nuclear transfer technique; and germ cells voluntarily donated. Thus there is a very big leeway given to scientists in deriving embryonic material for research. The limit is set at 14 days, which applies to both in vitro and in vivo research. Article 6 provides that any blastula obtained by IVF, somatic cell nuclear transfer technique, mono-sexual reproduction technique or genetic modification cannot be cultured in ex vivo for longer than 14 days from fertilization or nucleus transfer.

Wang endorses the support given in the guidelines for embryo research using somatic cell nuclear transfer technique, as well as the support for human embryonic stem cell research within 14 days, notwithstanding objections expressed both in China and in some foreign countries. She argues that an embryo within 14 days is not a person, but merely a human biological life. While she accepts that the human embryo has a value and deserves due to respect, it can be used for research if there are enough reasons for its use. In other words, the respect deserved by a human embryo before 14 days is not the same as respect deserved by a person. She cites the utilitarian position that very early embryos do not have even a rudimentary nervous system, have no sentience, cannot feel pain, or be hurt, and cannot suffer as a result of the research. She also says that because an embryo is not a person and does not have regard for itself as a end, it does not suffer from what others do to it. (Presumably, she excludes those situations when an embryo survives harmful research and thus survives until it is capable of suffering that harm.)

Wang holds that although the embryo within 14 days warrants serious moral consideration as a developing form of human life it does not have the same moral status as infants or children. To support her position, she cites the absence of developmental individuation, the lack of even the possibility of sentience and most other qualities considered relevant to the moral status of persons, personhood, and the very high rate of nature mortality at the particular stage. Nevertheless, the embryo merits respect as a developing form of human life. Hence, it should be used in research only for the most serious and compelling reasons. Research should be limited to the shortest time period, without being permitted beyond the time of the usual appearance of the primitive streak (14 days) in vivo. Moreover, the number of embryos required for the research must be kept to the minimum consistent with scientific criteria for validity.

Michael Cheng-tek Tai deals with biotechnical development that has been integrated with economic intent. He describes the economic context within which biotechnological advances have been crafted in Taiwan. Noting that the rapid growth propelled through the Taiwanese economic miracle has gradually slowed down in the last several years due to the relocation of many factories to China and the competition provided by newly raising developing nations, he echoes the need for a new direction to ensure continuity in economic development. This new direction is now being sought through biotechnological advancement. Fortification of biomedical research and the establishment of a biobank are thought indispensable to achieve this goal and projects to upgrade Taiwan's industries have been underway.

As may be expected, the establishment of a biobank has worried human rights groups. The latter have called attention to the need to safeguard the privacy of donors. They have also raised questions concerning the disposal of leftover superfluous tissues from experiments. Tai discusses the issues in his article, taking note of the measures that have been proposed by government to deal with the various concerns. Research institutes have indicated their awareness of the importance of the first issue and have promised to try everything they can to respect the privacy of stakeholders. The second concern is more complicated and controversial. Critics have not been assuaged by assurances that the consent of donors will be ensured. A major disagreement focuses on the clause in the Consent Form that asks donors to grant researchers the right to use leftover tissues for "future unknown" experiments. Once again, what surfaces here is the idea that bioethics ought to be regarded as forethought rather than as a mere afterthought regarding ethical issues after the events have taken place. The critics appear to have refused a formulation that leaves so much of the "future unknown" to chance. Indeed, the ability to chart direction for scientific discovery is minimized when things are left to chance.

Soraj Hongladarom's article describes the emerging ethics of bioinformatics as an amalgam of the two major strands of applied ethics. This is no doubt an apt description, but perhaps the interaction between bioethics and computer ethics requires a more dynamic analogy. In many emerging areas, one could say that bioethics is nourished by computer ethics but also that computer ethics derives substance from bioethics. As Soraj says, it remains to be seen how the new field actually turns out. It is likely to employ the tools and techniques that are already developed in both computer ethics and bioethics and, in the process, enhance those tools. This inevitable process of enhancement is part of the reason why boundaries between disciplines such as applied ethics, bioethics, computer ethics and so on are not set objectively. These fields of inquiry are defined through their subject matter and the tools that they use. As the subject matter and the tools change, they gradually pick up more and more of one another's characteristics and thus resemble one another more – not only in their subject matter, or their tools, but also in the goals that the practitioners set for their disciplines.

Significance for this last observation lies in the enhancement that the ethics of bioinformatics provides in order to realize the target of bioethics as forethought. One of the reasons why information is valuable is that it enables people to anticipate better – to predict outcomes and thus, possible ethical consequences. As information enhances the power of anticipation, it also helps to promote bioethics as forethought.

It is useful also to reiterate Soraj's observation that not too long ago, philosophers did not see applied ethics as a mainstream enterprise. Until the advent of bioethics, ethics was more concerned with ethical theory and with 'metaethical' analysis. To many traditional philosophers, ethicists had no business to pronounce judgment on the contemporary issues of the day. Perhaps it is the concern with bioethics as forethought that has convinced ethicists to pay more attention to bioethics. With bioethics as forethought, one is able to bring applied issues closer to timeless issues that had been the preoccupation of the Greeks and the ancient Eastern philosophers. In this collection of articles, one would do well to see how the idea of bioethics as forethought surfaces in various ways.

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Asian Bioethics: Theoretical Background

Editorial Introduction

Ciriaco M. Sayson, Jr.*

In the last few hundred years moral philosophy, at least in the Western world, has become largely the professional concern of academic philosophers, whose work has consisted in proposing and justifying the norms that explain and elucidate moral experience. The main *normative ethical theories* have often been presented as complete explanations for every conceivable moral problem and situation.

Immanuel Kant had proposed an ethical theory centered on the notion of *duty* as the definitive type of moral obligation. Kantian ethical theory relied heavily on the twin notions of *reason* as a pure faculty capable of intuiting the form of universal laws of moral action (the so-called *categorical imperatives*), and of the *will* as a rational faculty capable of motivating compliance with the deliberations of reason.

J.S. Mill, on the other hand, had argued for the foundational role of experience in identifying the norms of moral life. Mill found in the human experiences of pleasure and pain the ultimate grounds of the human aspiration for happiness, an aspiration which defines human beings as the moral beings that they are. Taking his cue from Bentham, Mill generalized this insight into the *Greatest Happiness Principle,* which proposes that an act is morally right in so far as it promotes human happiness. This tendency to promote human happiness is an act's *utility;* therefore utility is the criterion of the rightness of an action. Mill's *utilitarianism* held that utility is calculable, and that moral deliberation is accordingly subject to clear and rationally binding decision procedures.

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The contrasting Kantian and Utilitarian theories held sway in academic discussions until, in the 1950s, a few academic philosophers initiated a revival of *virtue ethics*, whose definitive expression had been Aristotle's *Nicomachean Ethics*. Aristotle () had held a notion of human happiness (*eudaimonia*) as the *flourishing* of human beings through the fulfillment of their specifically human capacities. This flourishing is possible only with the development in human beings of the moral excellences, or the virtues (*aretai*). The virtues are thus enabling characteristics of the human soul. They make it possible for human beings to achieve their fullest potentials as human beings in the requisite context of a life lived in political society.[1]

Kantian ethics, utilitarianism, and virtue ethics have now come to be recognized as the three fundamental normative ethical theories. They are also thought of as each embodying a distinct *type* of normative theorizing.[2] Their delineation as distinct theories, and the resulting ongoing debates on their scope and connections, have resulted in much theoretical clarity and understanding. Unquestionably, this philosophical achievement is of substantial value.

The Challenge of Applied Ethics

The rapid global advances in the technologies of medicine and information in the last several decades have posed significant challenges both for the professionals involved in these fields, and for moral philosophers. One might think that the challenges are all in the direction of applying the given theoretical molds to the concrete problems of medical practice and research, information technology, and so on. And yet few problems that come up in the practice of medical research, to take just one example, are resolvable by simply applying an ethical theory directly to the problem. For one thing, there are conceptual difficulties involved in the interpretation of just how the theory is to apply to the particular case, and even within a theory there are often conflicting analyses and resolutions of a case. How, for example, is the Kantian principle of human beings as *ends-in-themselves* to be applied to specific problems in bioethics, such as stem cell research? Or *should* it be applied there at all?

Ethical theorists who concern themselves with the biosciences also inevitably encounter existing practices that are questionable from the point of view of some ethical theory. But it is not always easy to label such practices *unethical* on that basis alone. In some sense, such practices are concrete embodiments of the *ethical life* of the community in which they are practiced, and are often in fact embedded in its laws and institutions.[3] An *ethics,* in this inclusive sense of being part of the *ethical life* of a community, stands in contrast to an *ethical theory,* the special domain of systematic thinkers such as academic philosophers. An ethical theory could turn out to be the product of systematic reflection on the ethical life of a community by persons who do not (or do not wholly) participate in that ethical life. To say this, however, is not to say that ethical theory is unilluminating; nor is it to say that moral practices are immune to philosophical criticism.

But it is hardly surprising, then, that there are no tidy philosophical solutions to many ethical problems in the biosciences. These problems arise out of the everyday life of communities; while they do not in principle resist ethical reflection, they are surely not *rooted* in that reflection. Rather these problems are rooted in practical activities in an institutional setting, with strong technological components. It seems best to view the relation between the existing practices, on the one hand, and philosophical theory on the other, as transactional rather than merely reflective in one direction.

There is a growing realization among moral philosophers themselves that problems in applied ethics compel a re-thinking of the very nature of philosophical inquiry into moral problems. Must such an inquiry take place in an intellectual setting that abstracts from real-world concerns, or which abstracts from the participation by these philosophers in the ethical life of their respective communities? Among moral philosophers there is now an increasing awareness of the situated nature of philosophical thinking. Moral philosophers can now ill afford to be only lightly informed about developments in technology, for instance—they take the risk, not so much becoming irrelevant, as of missing an opportunity for a critical encounter with the unstated assumptions of their philosophical practice. Only a philosophical practice that is critical of its own assumptions can hope to stay relevant to the real-world concerns of the biosciences and information technology.

At the other end, it seems fair to say that similarly, practitioners in the fields of the biosciences and information technology can barely afford to be unaware of how philosophical concerns impinge on their practices. There is an equally visible trend in the direction of more and more practitioners in these fields using concepts and arguments derived from philosophical theory to discuss, explain, and defend their practices. This is a salutary trend that bodes well for the future of these fields, and also for applied philosophy.

Applied Ethics and Institutional Guidelines

One response to ethical concerns arising in the fields of biomedical research is the adoption and publication of codified guidelines, rules and principles that will apply to the conduct of research in its multifarious aspects. This is true in general of areas of research practice that have strong institutional links, for institutions require monitoring of both procedures and results. Such guidelines invite critique and further discussion, and in this way a nexus for critical and philosophical awareness of underlying ethical values is set up, and a communication link is established between practitioners of these fields and professional philosophers.

As a result of this interaction, we can hope to better understand the prospects for a global bioethics, at least along the lines of some broad principles. Clearly some convergence of fundamental principles is possible. We can also expect to understand better the nature of the often sharp differences in cultural value that inform research practices across different societies, and the various intra-societal forces that contribute to these differences.

This Volume

The papers in this volume all contribute to this initial clearing of the field. The papers by Song Sang-yong (Korea), Yanguang Wang (China), Bagher Larijani and Farzaneh Zahedi (Iran), and Ryuichi Ida (Japan) present recently-formulated guidelines for stem cell and other embryonic research in their respective countries. The guidelines have prompted from the authors some serious and sustained reflection on underlying ethical issues in a recognizably philosophical manner.

The paper by Michael Cheng-tek Tai deals with the the current ethical debate in Taiwan on establishing a biobank, a genetic database that will enable future research on chronic diseases and the interaction between genes and environment. Frank Leavitt addresses the problem of genetically modified food seeds, and links his stand on this issue firmly with the ethical practice of Judaism. Leavitt presents challenging arguments that assign a wider scope to Bioethics vis-à-vis Philosophy. Soraj Hongladarom presents the convergent discipline of "bioinformatics," which brings together the conceptual tools of bioethics and computer ethics, and uses information technology to solve problems raised by biotechnology and biomedicine.

It is difficult to overestimate the value of a sharing of perspectives and insights among professionals from different fields. In this case, the sharing is particularly significant because it bridges a most crucial gap in human endeavor: the gap between activity or practice, and theory. These articles are bound by a common concern to bridge that gap and to intelligently confront the ethical challenges of a technologically advancing age.

Endnotes

[1] At the very beginning of Book I of the Nicomachean Ethics (1094a27-29), Aristotle declares the science of the Greek city state or polis (politike) "the most sovereign and most comprehensive master science" (Ostwald translation) . All human happiness or flourishing is possible only under the institutions of political society.

[2] While both Kantian ethics and Utilitarianism are both act-centered moral theories, Aristotelian virtue ethics is agent-centered. That is, Kantian ethics and Utilitarianism both start with the question, Which acts ought I to perform, and why? However, the two theories answer this question in divergent ways. Kantian ethics provides an answer in terms of the nature of moral duties; Utilitarianism proceeds to sketch a theory of the right-making consequences of actions. Aristotelian ethics, on the other hand, fundamentally asks, What kind of a moral agent ought I to be, and why? It replies to this question in terms of theory of a proper kind of life for human beings.

[3] In the Hegelian sense of sittlichkeit, which includes the laws and institutions of a community; in contrast to moralität as systematic discourse on ethical life, i.e., in the manner of ethical theory. See Hegel, Philosophy of Right sections 142-157.

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Genetically Modified Food Seeds: Health, Socio-economic, Environmental and Religious Aspects, An Israeli Perspective

Frank J. Leavitt*

Abstract: Although concerns about genetically modified (GM) food seeds are serious and well-founded, the problems which these seeds raise are usually not unique to GM seeds alone. GM organisms are only one example of problematic new varieties or breeds. Large soybean and other monocultural plantations have serious environmental effects which GM seeds exacerbate. Although GM seeds may benefit large scale commercial agricultural, these, and especially "terminator" and "traitor" genes, are a threat to small farmers. People have a right to know what they are eating, so labeling should be mandatory. Bioethics, like great philosophy, must grapple with the interface between science and religion. Spiritual and religious aspects of the GMO issue cannot be ignored. The question why corporations are investing in GMO technology will be discussed briefly because there is not much to say on the subject. There are viable alternatives to GM food seeds, especially organic methods such as the Kitchen Garden Scheme.

Keywords: Agriculture, Genetically Engineered Food, GMO, Judaism, Maimonides, Science and Religion, Spiritual.

Introduction

Although concerns about genetically-modified (GM) food seeds are serious and well-founded, the problems which these seeds raise are for the most part and with some exceptions, not unique to GM seeds alone. In Section II, we shall see that genetically modified organisms are only one example of the problematic new varieties or breeds of flora and fauna. We shall then (Section, III) discuss environmental effects of large

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The author wishes to thank Barbara Prainsack and Ze'ev Silverman for helpful comments on an earlier draft.

soybean and other monocultural plantations. This will lead us to comment, in Section IV, on "terminator" and "traitor" genes. In Section V, recognizing the right of people to know what they are eating, leads to a discussion on labeling. Some of the reasons which people have for wanting to know what they eat are spiritual reasons. Indeed, just as the great philosophers, with almost no exceptions, grappled with the interface between science and religion, so bioethics cannot ignore this challenge. So, spiritual and religious considerations will be discussed in Section VI. Section VII examines why corporations are investing in GMO technology. This will be the shortest section in the paper, because there is not much to say on the subject. Section VIII will consider alternatives to GM food seeds, especially organic methods with an emphasis being laid on the *Kitchen Garden Scheme.*

Unfortunately, there is not enough space to allow an in-depth discussion of the horrible impact of huge soybean plantations. These are displacing small farmers and Native Americans in Latin America, just as small farmers, tribal people, forest dwellers and others are being displaced for the sake of 'development' elsewhere in the world. Although non-GM soybeans can create the same problems, GM varieties have exacerbated the tragedy. As I have learned from Mr Edward F. Thiery, whose daughter Marcela has had first hand experience in Greenpeace demonstrations, those who are working for the rights of the Native Americans are threatened with violence by soybean interests. One nun has already been murdered. I have supplied references for the reader who would like to investigate this matter.[1]

Nor will there be adequate space to discuss risks to human health. These should not be ignored. The reader is referred to a WHO report expressing concern about *allergenicity, gene transfer* and *outcrossing.*[2] For a balanced discussion of other risks, the reader is referred to a paper by Watanabe and colleagues.[3]

Genetically-Modified Organisms as only One Example of Problematic New Varieties

Let us begin by putting the GMO controversy into context. Ethical problems concerning genetically-modified organisms are not entirely unique. They are special cases of general problems of new varieties or breeds of food crops and other organisms. These new varieties may have been the result of traditional methods of selective breeding or interbreeding in order to bring about flora or fauna which will be tastier or more aesthetically attractive or more useful for some purpose (such as a faster racehorse, or a bee which can pollinate more efficiently) than were previously existing breeds. Or they may have been the result of genetic engineering. Or varieties may be 'new' in the sense that although they have existed for a long time, they were only recently introduced into a specific eco-system. In order to see that some main issues in the controversy over genetically modified organisms may also arise over traditionally bred organisms, let us consider two examples: the question of the nutritional value of modern foods, and the question of introducing foreign species into an ecosystem.

The Nutritional Value of Modern Foods

Just before giving a lecture on the GMO controversy, I happened to notice in a supermarket an onion the size of a muskmelon. I bought it together with the smallest onion I could find, about the size of a cherry. I showed them to the students and presented the following thought experiment. Suppose that you plant 100 onion seeds of one variety, and 100 onion seeds of another variety, in the same garden plot. We shall assume that each of the 200 seeds has available to it the same amount of water, and the same amount of the same fertilizers (it is irrelevant to the thought experiment whether the fertilizer is organic or not). All other conditions: type of soil, temperature, etc, are also equal. The only difference is that the first group of seeds produce muskmelon sized onions, and the second group produce cherry sized onions.

Assuming that at the end of the growing season (the same length of time for both groups of seeds, of course) we get 100 muskmelon-sized onions and 100 cherry sized onions, I asked the students - almost all of them microbiologists - which onions would be the most nutritious per a given weight of onion. All seemed to agree that the cherry-sized onions would be the most nutritious.

The point seems to be obvious, If you breed plants (whether through genetic modification or through traditional breeding methods) for more yield per unit of input, you can expect puffed-up plants with less nutritional value. I do not know if this can be absolutely proven scientifically. But it is not surprising that recent research has shown that modern foods are less nutritious.

A 2004 study compared: "USDA nutrient content data published in 1950 and 1999 for 13 nutrients and water in 43 garden crops, mostly vegetables". The 43 foods showed: "apparent, statistically reliable declines (R < 1) for 6 nutrients (protein, Ca, P, Fe, riboflavin and ascorbic acid), but no statistically reliable changes for 7 other nutrients. Declines in the medians range from 6 per cent for protein to 38 per cent for riboflavin". The authors "suggest that any real declines are generally most easily explained by changes in cultivated varieties between 1950 and 1999, in which there may be trade-offs between yield and nutrient content".[4] A newspaper interview reports that Davis, the principal investigator in the study, 'who discussed his findings at a recent meeting of the American Association for the Advancement of Science in St. Louis, suspects the trend in agriculture toward encouraging crops that grow the fastest and biggest is a reason for the decline'. 'The tradeoff is that the faster-growing plants aren't able to acquire the nutrients that their slower-growing cousins can, either by synthesis or from the soil....'.[5]

It is perhaps debatable whether the reduced nutritional value is due to modern varieties of plants, or to chemical as opposed to organic methods of fertilization. Davis' data should really be compared to data on vegetables fertilized with compost rather than with commercial fertilizer. Although organic growers have often claimed that plants grown on compost are more nutritious than those grown on commercial fertilizer, this has not to my knowledge been proved. Davis' data should provide a good start towards designing a study for testing this claim. Until the claim is tested, however, it seems most reasonable to assume that the varieties of plants, rather than the methods of fertilization, are to blame for the reduced nutrition.

The trade-off between yield and nutrition in new varieties doesn't seem to depend upon whether the higher yield is achieved by genetic manipulation or by older methods of breeding. It would be a good idea, however, to do a similar study comparing nutritional content of GM foods with non-GM foods.

Ecological Impact of Foreign Species

Without yet touching on the question of genetically-modified organisms, we shall consider a further example of a problematic new variety. A variety can be 'new' in the sense that it never existed before.

It can also be 'new' in the sense that although it has existed in the past, it never before existed in a given ecosystem. An example is the bumblebee, *B. terrestris,* of which more than 40,000 colonies are imported into Japan from Europe each year. These bees are much more efficient pollinators than are native Japanese varieties. However, an article by Goka and colleagues points out that the introduction of *B. terrestris* into Japan may have undesirable ecological impacts of three kinds.

The first of the impacts listed by Goka and colleagues is competition for an ecological niche between introduced commercial species and native species. The second is the genetic disturbance caused by mating between introduced and native species. And the third and most serious impact is in carrying parasite invaders.[6]

I have intentionally refrained from touching on GMOs in order to bring out the point that reasons for concern about genetically-modified foods are only special cases of general concern about new varieties of organisms. If seeds, which have been bred by traditional means to produce greater yields, can also produce a loss in nutritional content, then so can seeds which have been genetically modified for greater yields. If there is reason for concern about the impact of introducing new traditionally bred foreign varieties into an ecosystem, there may also be reason for concern about the impact of introducing genetically-modified varieties into an ecosystem. The three forms of environmental impact mentioned with respect to the bumblebees are mirrored by similar causes for concern with respect to genetically-modified food seeds. This is obvious with respect to competition for ecological niches and with respect to the genetic disturbance caused by cross-pollination. And although there seems no reason to worry that GM seeds might introduce parasites, as did the foreign bumblebees, GM seeds carry other potential dangers.

Environmental Effects of Large Soybean and Other Monocultural Plantations

By 'monoculture' is meant the opposite of biodiversity in agriculture: the growing of one species of crop in a plantation, usually a large plantation. Monocultural plantations are much more susceptible to insect attack than are biodiversified plantations because there is no mixture of species to confuse the smell for predator insects. Insects that prey on a specific species will be attracted in large numbers to feast and breed.

Monoculture, therefore, requires more pesticides than do diversified plantations. Selling the pesticides brings further profit for the corporations. Pesticides are often serious environmental pollutants. Organic farmers, on the other hand, like indigenous small farmers who learned organic methods from tradition and trial-and-error, use "companion planting" - the judicious mixture of species in the same field - to produce a situation in which one plant repels the insects which threaten its neighbour. This is one of the organic alternatives to pesticides. Companion planting can also increase production: one example is growing legumes, which increase nitrogen in the soil through a symbiotic process involving nitrogen-producing bacteria, alongside plants like maize corn which have high nitrogen needs.

Conversion of forests, savannas and jungles to large plantations results in 'habitat loss', which has been described as the dominant cause of the loss of biodiversity. But the biodiversity of fauna is important to human health. One way in which fauna biodiversity reduces human disease is what is called the 'dilution effect'. Insect vectors that transmit pathogens, "only take a limited number of bites in their lifetime; when some of these bites are taken from hosts that are not competent to amplify the pathogen, these bites are wasted. This reduces the rate at which the pathogen is transmitted".[7]

Again, we are not discussing a problem which is unique to GMOs, but a problem which GMOs have the potential to exacerbate, due to their programmed suitability to large, monocultural plantations to which biodiverse forests, jungles and savannas are sacrificed.

On the other hand, one article argues that GMOs can contribute to biodiversity. "The possibility of adapting GM crops to conditions currently marginal for farming", the authors say, "could also be highly advantageous for biodiversity conservation".[8]

I do not understand, however, why GMOs should be needed to grow crops in "conditions currently marginal for farming". June and I had five years of experience in converting a multiple growth forest to rich soil for organic vegetable gardening in New England and upstate New York. By multiple-growth, I mean forest land which was cut for timber, used for farming or pasture, allowed to return to forest, cut again for timber, and so on through many repetitions. Not much soil is left after such a history. Yet, we used such methods as composting (making fertilizer by aerobically rotting organic matter) and green and brown manuring (planting crops not for the purpose of harvest but to be plowed back into the soil, either when they are still green or after they are dry and brown, in order to add organic matter, nitrogen, and other essentials of organic gardening). Our New England garden was for personal use, while the upstate New York garden provided food to a summer camp and nature education centre. Both gardens were very successful with no GMOs.

When Jews began to return to Israel in large numbers over the past hundred or so years, they found that the Biblical Land of Milk and Honey had been turned into a desert by two thousand years of unrestrained sheep and goat grazing by nomadic tribes. The Israeli miracle of making the desert green is known all over the world. When we were in the Sinai Desert, from after the 1967 war until we gave it to Egypt in the late 1970s and early 1980s, we turned vast areas of sterile sand dunes – conditions worse than "marginal for farming" – into rich agricultural land. I participated in this for two years as a member of Kibbutz-Moshav Atzmona. Under difficult conditions we were so successful as to have the earliest melons on the European market each spring.[9] If we had the chance, we could turn other deserts into rich, biodiverse agricultural land, with no need for GMOs.

"Terminator" and "Traitor" Genes

The problems discussed in this section are unique to GMOs.

Imagine a farmer who is not very sophisticated about biotechnology. He buys some grain which he has heard produces very high yields. Indeed, the crop is unusually successful. Like a good farmer, he and his family eat some, sell some, and save some for seed for next year. The next year, he works hard plowing, planting and fertilizing. But there is no harvest. Nothing comes up because these seeds have a 'terminator gene'. This is a gene which ensures that although a seed will produce a plant, and that plant will have seeds, this second generation of seeds will be sterile. The 'terminator' gene further ensures that the farmer will not be able to save seeds successfully for the next year, as farmers have done for thousands of generations, but will have to continue to buy seeds from the company.

In 2001, India banned the sale of seeds containing 'terminator' technology, and the ban was reconfirmed in 2005.[10]

'Traitor' genes seem worse than 'terminators', according to website reports. For example: '...Novartis explicitly claims the introduction of 'traitor' traits by the deactivation of essential, natural resistance functions of plants. By linking this deactivation to inducible promoters, patented plants can be sold that will not exhibit natural positive traits like germination and pest resistance unless exposed to a chemical. Novartis blandly calls it 'inactivation of endogenous regulation.' According to the company, the technique results in plants in which 'genes which are natively regulated can be regulated exclusively by the application to the plant of a chemical regulator.' In other words, the plants are effectively drug addicted....'.[11]

However, although these reports about 'traitor' genes seem reliable, I have not succeeded in finding information about them in peer reviewed, scientific sources. So I cannot endorse the reports. With respect, however, to 'Terminator' genes, which as we have seen are banned in India, I have been to a large number of conferences in which these genes were discussed from many scientific and ethical angles, so that the information which I have quoted seems incontestable.

Labeling

People may have various reasons for objecting to eating certain kinds of foods. The reasons may have to do with health, the environment, socio-economic issues, cruelty to animals, and spirituality.

Religious Jews refuse to eat a number of foods for spiritual reasons. These include, among others, meat or milk from animals which do not chew the cud and have a cloven foot. Hindus, for spiritual reasons, will not eat beef. Indian Ayurvedic medicine claims that beef has a bad effect on personality traits. Many Hindus abstain not only from beef but from all animal, poultry and fish flesh. Jains are not only vegetarian, but they abstain also from roots, like potato, onion and radish. We may or may not agree with these various kinds of abstention. But surely people have a right to make their own decisions about what they don't want to eat. And for the decision to be a free one, they have a right to know what they are being offered or sold.

It seems clear that GMOs exacerbate socio-economic and environmental problems. We do not know enough yet to draw a clear conclusion as to whether they are dangerous to human health. Nor can we say for sure that they present a problem for spirituality. But surely people have a right to make their own decisions about these matters. So GM foods and seeds ought to be labeled as such.

Several years ago, I attended a seminar in Jerusalem on GM foods, conducted by Mrs Ofra Strauss, the owner of the Strauss Company, (now called Strauss-Elite) which produces cheeses, ice cream and other dairy products, as well as humus (ground chickpeas). Humus, as well as falafel (also made from chickpeas) are the Israeli national food. Mrs Strauss told us that her company will not buy milk from genetically engineered cows, or from cows which have been eating genetically engineered feed.

When I prepared a lecture last spring on GM food seeds, I decided to find out how well the Strauss Company has been able to maintain Mrs Strauss' ideals. I learned by telephone that their humus was not genetically engineered. Later, on 17th April 2006, I received an email from their representative, Yossi Kozay, saying: "Raw materials [which Strauss uses] from genetically engineered plants are usually varieties of maize corn and soy which are principally grown in North America. Most of the genetically engineered crops withstand disease better, and produce a larger harvest. We buy from the United States. So it is impossible to know if the raw material is genetically engineered or not, because there is no law about this, and no requirement of labeling.

Spiritual Considerations

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It may seem incongruous to see a discussion of philosophical, religious and spiritual matters in the course of what is mainly a review of scientific and semi-scientific literature. Bioethics, however, faces to a large extent the same kind of challenges which philosophy faced in its great days: challenges of apparent or real contradictions or tensions between science and religion.

The great philosophers, from ancient times until up to at least the beginning of the twentieth century, were almost all learned both in the science of their times and the religion of their peoples. I think this is equally true in Western and in Asian philosophy. I do not think that one can understand Ayurveda in isolation from Hinduism. Nor can one understand Plato and Aristotle without knowing something of Greek science and religion. Descartes was a mathematician, physiologist and physicist with a sound knowledge of Catholicism through his Jesuit education. Hume, although an atheist or close to being one, had a strong education in Presbyterian theology. And he knew enough Newton to attempt to base his psychology on a similar experimental method, while he grappled as well with paradoxes of infinitesimals. Bertrand Russell, mathematician, shows a serious interest in religion in his *History of Western Philosophy*. And his: *Why I am not a Christian* was not written from ignorance. This tradition of working in the interface of science and religion continued up into the first half of the twentieth century, until a new breed of philosopher, ignorant both of religion and of science and proud of it, began to take over: at least in English speaking countries. Gilbert Ryle, a deep philosopher in spite of it all, was able to decide that a study of the brain could teach nothing about the mind, without his having studied the brain.

Bioethics, which is not philosophy because it is broader than philosophy and includes philosophy as only one of its sources, includes a return to the great philosophical tradition of grappling with science and religion together.

This is appropriate especially with respect to GMOs. Where science has not yet answered our questions about whether they are good for us and the earth, and while it may never answer them, we must step outside of science and look at philosophical, social, religious and spiritual sources.

Prince Charles' critical statements on GMOs are well known (HRH, the Prince of Wales 1999). Many of his statements are quite consistent with material which I have found in a literature search seven years after they appeared, and to which I have referred in this paper. He says, for example: "The benefits, such as there are, seem to be limited to the people who own the technology and the people who farm on an industrialised scale". Later in the document, he says: "Before drugs are released into the marketplace they have to undergo the most rigorous testing.... But GM food is also designed in a laboratory for human consumption.... Surely it is equally important that we are confident that they will do us no harm?"

But I would like to emphasize some more philosophical remarks of his: "Are we going to allow the industrialisation of Life itself, redesigning the natural world for the sake of convenience and embarking on an Orwellian future? And, if we do, will there eventually be a price to pay? Or should we be adopting a gentler, more considered approach, seeking always to work with the grain of Nature in making better, more sustainable use of what we have, for the long-term benefit of mankind as a whole?" In spite of the rhetoric, Charles' questions are very important. Is nature created for the benefit of humans, so that we may do with it as we please? Or shouldn't we recognize the right of Nature itself to exist? Perhaps a cooperative, sustainable relationship with nature will be not only for the good of nature but for the good of humanity as well.

Charles was educated in the British, Christian tradition. But let us see what Judaism has to say about these issues. The Bible says that God blessed the first humans and said: "Be fruitful and multiply and fill the Earth, and conquer it, and have dominion over the fish of the sea, and the birds of the heavens, and of every creature which moves upon the Earth. (*Genesis I, 28*) But the phrase, "conquer it and have dominion", can be interpreted in different ways.

Some would interpret "dominion" in a quite despotic sense. The *Mishna*, in *Tractate Kidushin*, IV, 14, quotes Rabbi Shimon ben Elazar as saying that the animals and the birds "were created only to serve me, and I was created to serve my Creator (my translation). Rabbi Moshe ben Nachman ("Nachmanides", "Ramban" 1194-1270), commenting on *Genesis I, 28)* understood this verse as saying that God gave humans "power and dominion to do as they will with the animals and the lower creatures, and all which creep on the Earth, to build and to tear up what has been planted, and from the mountains to mine copper and similar thing." (My translation). These opinions are the basis for those who today are saying that there is nothing wrong with our interfering in creation and "playing God", because we humans are partners with God in creation.

On the other hand, Rabbi Moshe ben Maimon ("Maimonides", "Rambam" 1138-1204), who was Israel's greatest rabbi, philosopher, physician and bioethicist, says that the verse which we have quoted from *Genesis* "does not mean that man was created for the sake of this, but merely gives information about man's nature.... (Ben Maimon 1953, III, 13). As Maimonides goes on to explain, God – with few exceptions – does not create one thing for the sake of another. God creates each thing because God wants that particular thing.

An intermediate view is expressed in the Midrash, *Kohelet Raba* VII, I, 13. The Midrash is a rich ancient collection of stories, anecdotes, advice and Jewish Law: "When God created the first man, He took him for a tour of all the trees in the Garden of Eden. 'Look at my works,' He said, 'how pleasant and excellent they are. Every thing which I created, I created for you. Pay attention not to ruin and destroy my world. For if you cause ruin, there is no one who will repair your damages' (my translation). This story is beautiful but dangerous, because it can give us the prideful attitude that everything (with the lone exception of God) is for us. If we couple this attitude with the prideful attitude that technology can solve all of our problems, we are easily on our way to taking more environmental risks. Haven't we polluted our air, soil and water enough?

Lynn White Jr's famous 1967 article, which blamed Jewish and Christian theology for "the historical roots of our ecological crisis" was partially right.[12] As we have seen in Nachmanides and in the *Midrash*, there are Jewish sources which can lead to a domineering attitude towards nature. But Judaism is a vast sea of sources which very often don't agree with one another. This is because Judaism is an open-minded, non-dogmatic religion which encourages freedom of thought and opinion. We don't have one prophet. We have many prophets, and new prophets can arise in each generation. We don't have a Church hierarchy. We have rabbis, who are regular humans who often (although not always) have learned more than those who are not rabbis. We are all encouraged to learn, think and discuss, using the intellect which God gave us. The Jewish sources, which suggest that nature is created for us, and that we can do with it as we please, are not the only Jewish sources. Nor are they the most important of the Jewish sources on our relationship to nature.

Maimonides, who as we have seen did not believe that nature is created for us, had a very animistic, almost pagan attitude to nature. For me, however, 'pagan' is not a pejorative term.

At one time I compared Maimonides' philosophy of nature to Aristotle.[13] Today, I would rather compare his philosophy of nature to ideas of the divinity of nature in Shinto. I see Judaism as more similar to Asian national and tribal religions than to Western thought.

Maimonides refers to nature as: "...wise, having governance, caring for the bringing into existence of animals by means of an art similar to that of a craftsman, and also caring for their preservation .... (Ben Maimon III, 13, p. 455) In his *Guide to Health* he says that nature is: wise and crafty, it will do what is necessary and has no need for others [to help it] to cure the sick (Ben Maimon 1957a, I, 44). In his treatise, *On Asthma,* he says in the Hippocratic tradition that nature is educated in good ethics, for it is from nature that we learn ethics (Ben Maimon 1957b). In his *Medical Aphorisms*, he accepts Galen's doctrine that whenever there is a doubt about how to cure a patient one should leave him or her to nature, for nature knows the proper balance of the organs, provides each organ what it needs for health, and keeps living creatures healthy and cures them of their sickness (Ben Maimon 1957c).

Maimonides didn't know about GMOs. So we cannot say what he would have thought about them. If, however, we combine Maimonides' respectful, animistic view of nature, together with his denial of the doctrine that nature was created for man, a strong conservatism about tampering with nature is suggested. Of course, Maimonides never said that we are never to tamper with nature. With respect to treating patients, it was only when in doubt that he recommended letting nature take its usually – but not always — healthy course. When nature alone is inadequate to curing a patient, he recommended a change of diet and other habits or, in more extreme cases, medicine. But GM food seeds are a matter of doubt. There are clear social, economic and environmental threats. It is still doubtful whether these threats can be overcome. And freedom from direct threats to human health is still a matter of doubt. So I would think in the spirit of Maimonides, that we should take an extremely conservative position towards GM food seeds, and probably even forbid them. The situation may be different with respect to genetically engineered drugs *if* they are proved to be safe and effective. Human gene therapy *may* also sometime be proved to be safe. But genetically modified food seeds, about which there are so many doubts, are a different matter.

The fact that even one of the very greatest of the rabbis said something, does not make it true. Is Maimonides right about our relationship to nature? He says that God did not create one thing for the sake of another. But how does Maimonides know what God has in mind? How can we know whether Maimonides' interpretation of the Bible is any truer than the interpretations of rabbis who thought that God created nature for the sake of man? All rabbis have the same holy sources available to them. Any issue on which two of them can contradict one another cannot be unequivocally decided on the basis of holy sources. This is especially true when it comes to knowing anything about God. "And He said, Thou canst not see my face: for there shall no man see me, and live" (*Exodus* XXXIII, 20). "The secret things belong unto the Lord our God: but those things which are revealed belong unto us and to our children for ever, that we may do all the words of this Law." (*Deuteronomy* XXIX, 28, King James translations with my minor revisions). My humble opinion is that when it comes to issues like what God has in mind, nobody can know the answer.

Our recognition that we have no way of knowing the deepest meaning of life, or God's purpose in creating the world and its creatures, should lead us to humility. Being small creatures ourselves. totally ignorant of the deeper things, how can we dare be so prideful as to take it into our hands to make radical changes in something so fundamental to nature as the genomes of flora and fauna, especially when such changes have no scientifically proven human benefit? This is especially pertinent after our record of global environmental failure.

Why are Corporations Investing in GMO Technology?

A few years ago I attended a bioethics seminar in Japan. Novartis-Japan was invited to send a representative. During the discussion of GMOs, someone asked the representative why Novartis is investing in GMO technology. She answered: "Because we think that it will be profitable."

Alternatives to GM Food

Let us begin with another quotation from Prince Charles: "How much more could we achieve if all the research funds currently devoted to fashionable GM techniques - which run into billions of dollars a year - were applied to improving methods of agriculture which have stood the test of time?"[14]

I would like to add: "And methods of agriculture which would serve the majority of the needy people in the world".

It does not serve the needs of people to force or entice them out of their small farms, their forests and their jungles to make space for 'development', and then – if they survive at all – to put them in a situation of having to choose between being starving urban homeless or working at unhealthy, undignified jobs in order to buy the products of the same 'development' which destroyed their traditional lives.

People in rich, highly technological and materialistic countries find it difficult to distinguish between simplicity and poverty. Unhappy, sick people living on the streets in big cities are poverty. Happy, healthy families living in houses with dirt floors, mud and straw walls and straw roofs, making their living from hard work with their own animals and their own tiny farms, are simplicity. I have never seen such happy people and gracious hosts as a family of this sort with whom I stayed a night in Velhe Block, Pune District, Maharashtra. They were so isolated that even our Jeep could not reach them. So we walked through the monsoon mud for the last bit of the journey. In the evening we all sat in a circle on the mud floor. The women sat by the fire and passed us hot, freshly cooked food and freshly fried chapatti. They did not lack in spiritual life, being active in the local Hindu temple. The grandfather was renowned in the area for successfully growing plants which no one before had been able to grow in that area. Their daughter is a Prabhodika, a 'Spreader of Light', working in a project of the Jnana

Prabhodini organization in Pune, teaching village mothers about improving nutrition, hygiene and midwifery, and helping them set up home crafts businesses. Later, each took a blanket, found a place on the floor and went to sleep. In the morning I went to the rain drain to wash. A child came out and proudly presented me with a small sliver of soap. People in rich countries who think that there is something wrong with you if you don't get a new car every few years, are incapable of understanding that this is not poverty.

I have already quoted Prince Charles, who suggested investing those "billions of dollars a year...[into] improving methods of agriculture which have stood the test of time." For me this would mean helping millions of people to achieve what that family has achieved, and helping them to improve what they are doing even more.

One example of an alternative to GMOs, a plan for improvement, is the Kitchen Garden Scheme: an integrated system involving anaerobically composting human and animal waste, to produce biogas for cooking. When the anaerobic compost is finished, more organic matter is added and the pile is composted aerobically to produce rich fertilizer for the home garden.[15] Composting human and animal waste radically improves sanitation and hygiene. It also prevents the rains from carrying these wastes off to pollute water supplies. The compost privy, replacing free defecation, prevents parasite infections to children going barefoot among the "night soil". And parasites are a major cause of underweight. Cooking with biogas rather than solid fuels on indoor fires prevents smoke inhalation. A higher vegetable content in the diet fights iron deficiency among other problems. Indeed both allopathic and Ayurvedic doctors whom we interviewed in a health survey in Maharashtra in 2000 indicated a lack of vegetables in the diet as a major cause of disease.[16]

Yet, underweight, unsafe water, sanitation and hygiene, iron deficiency, and interior smoke caused by the burning of solid fuels are five of the eleven most important risks to health today, which were listed by Gro Harlem Brundtland, Director General of the World Health Organization, in her Message included in the 2002 World Health Report.[17] Can anyone seriously say that GM foods have such a potential for improving human health?

The Kitchen Garden Scheme is only one of the many potential ways to improve traditional agriculture as alternatives to GMOs. But this paper can not provide more details of this, except to mention that perhaps the first priority has to go to returning the mountains, the jungles, the deserts and the forests to their traditional inhabitants.

Endnotes

[1] Altieri (2006); Greenpeace (2006a, 2006b).

[2] World Health Organization (2006).

[3] For more details see, Watanabe, Sassa, Suda, Chen, Inaba, Kikuchi (2005).

[4] Davis (2004).

[5] Gay (2006).

[6] Goka (2001).

[7] Dobson (2006), Keesing (2006).

[8] Connor (2003).

[9] Leavitt (1993).

[10] Anon (2005).

[11] Guidetti (2000).

[12] White (1967).

[13] Leavitt (1998-1999).

[14] HRH The Prince of Wales (1999).

[15] Leavitt (2005).

[16] Tanabe (2001).

[17] World Health Association (2002).

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The Debate on Establishing a Biobank in Taiwan

Michael Cheng-tek Tai*

Abstract: The purpose of a biobank is to gather and study the genetic information of a group of people to understand their genetic formation and discover whether or not some inherited diseases are present so that measures can be taken either to repair or alter these defects. In order to do this, extraction of blood from people is required. How much tissue should be taken has been an issue of concern to some ethicists while other human right groups also argue that this biobank should not be established at all because it runs the danger of breaching personal confidentiality.

This paper brings up these concerns and argues that no extra blood sample should be taken if this biobank is to be established. A survey of some medical students views on so-called "left-over tissue" was also undertaken.

Keywords: Biobank, Leftover Tissue, Human Right, Biotechnology.

The so-called economic miracle of Taiwan in the last few decades was the pride of the Taiwanese people. The rapid economic growth propelled by this miracle has.however, gradually slowed down in the last several years due to the relocation of many factories from Taiwan to China as also due to the competition posed by newly - arising developing nations in the world. To ensure a continuous economic development, Taiwan therefore, needs a new direction while the computer industry is one such option that has brought much wealth in recent years yet Taiwan cannot depend solely on it; thus it has explored the emerging field of — biotechnological advancement.

To achieve this goal, fortification of biomedical research and the establishment of a biobank and other measures are considered indispensable. Projects to upgrade Taiwan's industries have been underway. The establishment of a biobank, however, has worried human rights groups as well as some scholars over issues such as,

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first, safeguarding the donors' privacy, and second, the disposal of the superfluous tissues left over from experiments. Responding to the first concern, the research institutes have indicated their awareness of the importance of this and they have promised to respect the privacy of every donor. The second concern is more complicated and controversial as the researchers insist that as long as the donors consent to the use of the leftover tissues, it should not be a problem. The human rights groups and some ethicists argue that a clause in the Consent Form that asks donors to grant researchers the right to use leftover tissues for future unknown experiments is a clear violation of ethical norms.

When asked for justification for establishing such a bank, Dr Chen Yuan Tsong, the head of the Institute of Biomedical Sciences at Academia Sinica and a key player of ELSI (ethical, legal, social issues) within the National Human Genome Research Institute, replied: "To build Taiwan's biological database in order to look into the factors causing common chronic diseases in Taiwan and to understand the impact of the interaction between genetic and environmental factors on such diseases in order to establish effective treatments and preventive strategies to safeguard the health of people in Taiwan". The study design used in developing this biological database is called a prospective cohort study, he explained, and risk factor information will be collected to observe whether those who are exposed to risk factors have a higher risk of developing a disease. Obviously, the establishment of this biobank is research-oriented but due to the long-range nature of this project, some donors may not live long enough to see the result. In that case, are their biological data to be destroyed or to become the property of the institute that carries on the research?

The underlying objective to establish such a biobank is indeed noble, yet how are we to safeguard the bioinformative privacy? One of the key members of the biobank project argued that rights have two natures, one is individualistic, and the other communitarian, meaning society owns its bioinformation. Informed consent, he argued, should be approached from both ends, namely, individual informed consent and community informed consent. He further stated that the community has the right to decide what genetic information should be shared by all and what belongs to the individual.

In order to motivate people to participate in this research, a free physical examination has been promised to those participants who consent to this study by donating their tissues for research. Again, the question is raised that this attempt to promote tissue donation violates the principle of justice that states that no coercion or enticement should be used to influence a voluntary decision.

To ensure that all the concerns are considered and explained, Taiwan's Ministry of Health has launched an attempt to formulate a research ethics for tissue procurement. No research can be carried out without being first approved by the Institutional Review Board (IRB). This proposed regulation, however, allows the leftover tissues to be used for other experiments provided that the research protocol has first been reviewed and approved by IRB. Some bioethicists worry that the clause on "leftover tissue tolerance" will surely motivate the researchers to extract more tissues than needed so that they can store them for later use. Although the regulation indicates that use of leftover tissues should also be approved by an IRB before the actual experiment, the concern remains — should a scientist be allowed to extract more tissue than needed? This "leftover" regulation seems to insinuate that the extra-tissue-taken is permissible despite the fact that the regulation emphasizes that none of the research including the procurement of organs or body tissues should violate medical ethics. This statement is vague, leaving room for subjective interpretation.

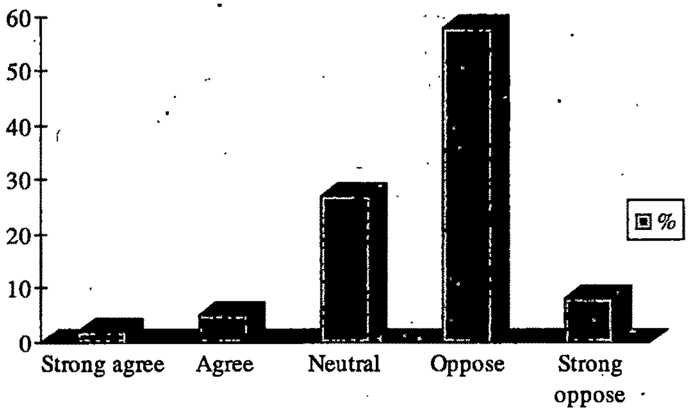
The use of fresh cadavers for research poses yet another issue. The proposed regulation indicates that cadaver tissue can only be collected after proper consent is sought and received. The representatives from the Prosecution Office participating in the discussion voiced their dissent, as this will jeopardize their criminal investigation when enforced because some criminal investigations are also research-oriented. Who owns the cadaver? Is it private property or does it belong to society? Who is to give the consent? In a Confucian society where decision-making is family-oriented, the attempt to obtain this consent may set family members at odds against one another.

The establishment of a biobank is indispensable for the advancement of biotechnology but ethical concerns expressed by some scholars must be addressed. A public hearing to explain the purpose, function and ways of operation needs to take place. The expressed concerns are not groundless. Irresponsibility in biomedical research must not be taken lightly.

An interesting survey in regard to this 'leftover tissue' issue was conducted in May 2006 at the Chung-kuo (China) Medical University in Taichung using 5th year medical students as respondents. This survey shows that the majority of medical students oppose the storing of leftover tissue for future research. Three scenarios were given to which varying responses were sought of 112 students in class:

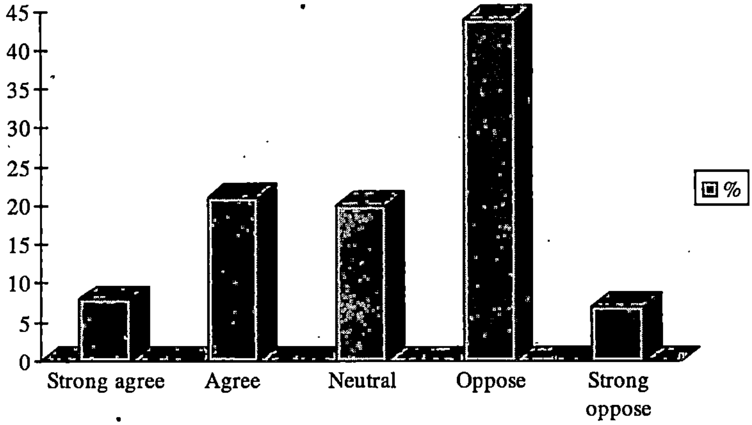
1. For biomedical progress, the research may extract more sample-tissue than needed to be stored for future experiment.

Strong agree	2 %
Agree	5 %
Neutral	27 %
Strong oppose	8 %



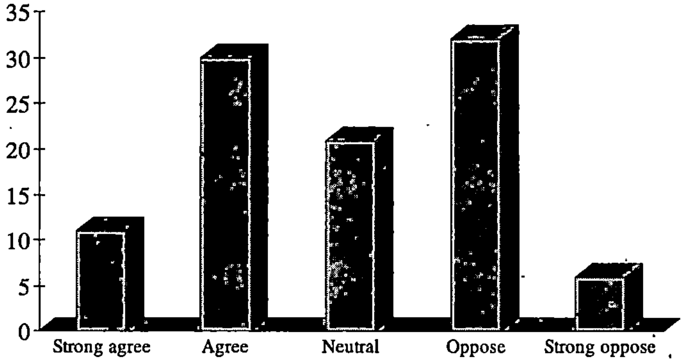
2. For biomedical progress, the researcher after telling the donors may extract more tissue than needed to be stored for future experiment.

Strong agree	8 %
Agree	21 %
Neutral	20 %
Oppose	44 %
Strong oppose	7 %



3. For biomedical progress the researcher after obtaining consent from donors may extract more tissue than needed to be stored for future experiment.

Strong agree	11 %
Agree	30 %
Neutral	21 %
Oppose	32 %
Strong oppose	6 %



These ethical concerns remain unsettled. The Academia Sinica in charge of this project has tentatively suspended this project. Its IRB is still reviewing the experiment proposal presented by the researchers.

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Ethics of Bioinformatics: A Convergence between Bioethics and Computer Ethics

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Abstract: The emergence of bioinformatics as both a field of study and a system of practice has also given rise to a convergence of bioethics and computer ethics, which are the two major strands in applied ethics nowadays. Such a convergence calls for a reflection on the methodological point of what actually constitutes either bioethics or computer ethics as a way of deliberating about normative issues arising from advances in the technology. Moor's view that computer ethics should be independent from traditional ethics is discussed. This problem is further exacerbated by the rise of bioinformatics. It is proposed that the distinction between computer ethics and bioethics is arbitrary from the beginning; hence the emerging ethics of bioinformatics will perhaps always retain its provisional character.

Keywords: Computer Ethics, Bioethics, Bioinformatics, History, Academic Discipline.

Introduction

Bioethics and computer ethics are two main branches of what can be called 'applied ethics'. Broadly construed, applied ethics is an attempt to use the vocabularies, theories and argumentative methods normally used in philosophy to tackle 'real world' problems such as those of nuclear proliferation, pollution, economy and crimes related to these, as well as those traditionally associated with bioethics and computer ethics, such as abortion, euthanasia, cloning, privacy, hacking, copyright issues, and so forth. The list is endless, since applied ethics deals with any social or ethical issues that crop up when we are faced with problems of value. It is self evident that applied ethics are highly important, even necessary, in today's world when we are faced with a

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plethora of problems not seen before. However, applied ethics was not individually distinguished as an area of study by philosophers earlier, as ethics was then more concerned with the 'metaethical' problems to do with the analysis of evaluative concepts and on ethical theories in the line of, say, Kant or Mill. To these traditional philosophers, ethicists have no professional business to pronounce any judgments on the contemporary issues of the day; instead ethicists should pay more attention to the timeless issues in the field, such as how the term 'good' is defined, or how objective ethical judgment is possible. Nonetheless, many philosophers have become rather uneasy with these ways of thinking about ethics, because this would mean that ethics, and philosophy in general, tends to divorce itself from the issues that grip the society around them. Since ethics deals directly with what should be done, it is all the more surprising to see traditional ethics shunning this first-order question and focusing its attention on purely conceptual and theoretical problems. Applied ethics arose as a response to this traditional trend, and nowadays it has established itself as a field in its own right.

What applied ethics aims to accomplish then, is to provide the public with first-order ethical judgments on a number of contemporary issues of relevance. For example, during the Cold War when the threat of nuclear annihilation was palpably real, many philosophers raised their voice to pronounce their professional judgments on the topic. This was done not merely from their status as citizens in a democracy, to which everybody is entitled, but rather in their capacity as philosophers. That is to say, philosophy or ethics is used to tell the public what ought to be done, something that philosophers in the West had avoided doing since the time of the positivists or earlier. Philosophical vocabularies were employed and as a result issues which had been murky became much clearer when flooded with the spotlight of philosophical analysis.

The emergence of bioethics and computer ethics clearly illustrates this trend. According to Robert Martensen (2001), the term 'bioethics' was first used by Sargent Shriver in his living room in 1970, when he and his wife met with Andrée Hellergers, then President of Georgetown University and discussed the idea of establishing an institute "for the application of moral philosophy to concrete medical dilemmas" (p.

168). It is clear, then, that bioethics emerged out of the need for philosophical reflection on the problems posed by modern medicine. On the other hand, James Moor, whom many regard as the father of computer ethics, wrote that computer ethics arose as a response to the emergence of computers as the technology that defines contemporary society.[1] Computers, and more recently the global network such as the Internet, have had a tremendous impact on the lives of many people. The technology is at least as powerful scope to alter human society as is modern medicine or the life sciences. Consequently, as biotechnology and biomedicine, as well as computer technology are increasingly penetrating perhaps every aspect of our physical and social lives, it is clear how bioethics and computer ethics are the two most relevant branches of applied ethics today.

Computer Ethics

An interesting topic of discussion and debate in computer ethics is one concerning its status as an autonomous field of study. According to Moor, the field needs to be autonomous, since the nature of computer technology is such that dealing with it adequately requires that the attempt to employ novel conceptual tools. He goes on to say:

> The mark of a basic problem in computer ethics is one in which computer technology is essentially involved and there is an uncertainty about what to do and even about how to understand the situation. ... In one sense I am arguing for a special status of computer ethics as a field of study. Applied ethics is not simply ethics applied. But I also wish to stress the underlying importance of general ethics and science to computer ethics. Ethical theory provides categories and procedures for determining what is ethically relevant. ... On my view, computer ethics is a dynamic and complex field of study which considers the relationships among facts, conceptualizations, policies, and values with regard to constantly changing computer technology. Although computer ethics is a field between science and ethics and depends on them, it is also a discipline in its own right which provides both conceptualizations for understanding and policies for using computer technology.[2]

The idea is that when computers are essentially involved, there seems to be a need for a special kind of tools that can adequately deal with case. Such a set may include discussions on the nature of computer and information technology. When a burglar comes into a house and steals a computer, that does not constitute a problem for computer ethics, but when a hacker uses his expertise to steal a lot of personal data, that is a problem. Deliberating effectively on the ethical evaluation of the latter action requires that one possess a set of conceptual tools which are not available for the former case.

Bioinformatics

What is special in the case of bioinformatics is that it is consciously an amalgam of these two powerful technologies. Simply put, bioinformatics is an attempt to harness the power of information technology and the Internet to solve problems posed by biotechnology and biomedicine. The success of the Human Genome Project, where the entire genome of human beings has been decoded, gave rise to attempts to harness computers to manipulate and process all the data that suddenly have become available. It is very curious to see how the two technologies are merged together. On the one hand there is the public perception of a computer scientist as a 'geek' who lives his (or her) entire life in front of a computer screen; on the other, there is the perception of a biotechnologist dressed in immaculate white with white masks holding a test tube. These two perceptions are getting blended into each other.

Ethical issues posed by bioinformatics are those concerned mainly with the use of computers to manipulate genetic data. Privacy is perhaps the topmost concern, but so are discrimination, genetic profiling, development of drugs that target specific individuals that might lead to stratification, and so on. These issues have been dealt with elsewhere.[3] In this paper, I shall discuss mainly the methodological issue. If these issues posed by bioinformatics are real and are relevant to our lives, then there will be an ethics that discusses them. But what should it be? Should it be computer ethics or bioethics? Or is this distinction between two major applied ethical activities rendered outmoded by bioinformatics? My answer at this point is that the distinction between the two 'ethics' is arbitrary from the beginning; hence, the question whether the 'ethics of bioinformatics' that will undoubtedly emerge should enjoy a special status of its own or whether it should be a species of either computer ethics or bioethics (or both) is an empty one. One can deal with the ethics of bioinformatics from a number of perspectives. There will most probably be a new special vocabulary se to deal with issues in bioinformatics, in the same way as there emerged such a special set with the other, older issues. But the point is that, since the issues themselves are getting mixed with each other, the disciplines that discuss them (the various ethics) are getting mixed up too, and thus it does not seem to make much sense to make a distinction among them.

The issue encourages a reflection on the difference between computer ethics and bioethics. Basically, the only difference there is seems to be that one discusses a certain range of problems, while the other discusses another. But if that is the case, then Moor's view that computer ethics employs a distinctive vocabulary set seems to be skimming only the surface. The special set seems in this case to be only that of the subject matter talked about, computer technology rather than biotechnology. However, Moor's point goes deeper. His view is that computer ethics requires a special set of tools and vocabulary that sets it apart from traditional or theoretical ethics. It is the nature of the computer itself that requires such a special set.[4] If this is so, then as bioinformatics requires a lot of computer use, its ethics should also be considered a part of computer ethics and thus, according to Moor, requires a special set.

What is interesting is that, in the case of bioethics, there does not seem to be much debate on its methodological nature, its distinction from traditional, theoretical ethics. There seems rather to be a tacit agreement among bioethicists that their discipline, at least its philosophical foundation, lies well within the domain of traditional ethics. Thus we hear philosophers such as Thomas Pogge or Onora O'Neill pronouncing their views on bioethical matters as if they were addressing a purely philosophical audience. Their use of tools and vocabularies lies fully within the mainstream of ethics or political philosophy, and they do not claim that what they are doing should be categorized as a new kind of ethics, in the way that a computer ethicist such as Moor would do.

There may be a reason behind this. Perhaps it is actually the nature of computer and information technology that prompts Moor and his followers to regard computer ethics as being of a special kind. After all, computers have a special characteristic in that they are a second-order device,[5] meaning that they do not deal directly with material objects in the world, but rather with *symbols,* which inside the computer are represented by whether the switch is turned on or off. In slightly abstract terms, this turning on or off is represented by the number 1 and 0, and it is not surprising that the mathematics of choice among computer scientists is the binary system. What is important is that these ones and zeroes are grouped together and manipulated in various ways, and they function not as themselves but as symbols for anything whatsoever. According to Moor, it is because of the symbolic nature of computers that computer ethics has to have the special status. On the other hand, when bioethicists such as Pogge, O'Neill or Singer air their views on bioethics, they usually do not concern themselves with the question whether bioethics should be an autonomous discipline or not. Their subject matter, whether it be informed consent, global justice, ways for pharmaceutical companies to act more responsibly, vegetarianism, and so on, seem to be the issues that ordinary people usually understand. In any case these issues are not symbolic ones. Even though bioethicists deal with a technology and its aftermath, such as when they deliberate upon the moral worth of genetic modification technology, these technologies are not second-order in the sense that computer and information technologies are.

Toward an Ethics of Bioinformatics

All of the above points to a rather odd case for bioinformatics. If we agree with Moor, then the ethics of bioinformatics is a part of computer ethics, but as a species of biotechnology it should belong to bioethics instead. Perhaps a way out is to find a way to fuse these two fields of applied ethics together, at least where bioinformatics is concerned. What we need to do is, of course, to keep the traditional conceptual tools belonging to traditional, theoretical ethics. These are indispensable. And then we devise a new subset which deals specifically with issues in bioinformatics. It is widely acknowledged that privacy is one of the most important ethical concerns in bioinformatics. Now the question is: Is the conceptual tool that is usually more or less adequate in dealing with privacy in normal domains of computer ethics (stealing identity through hacking, and others of such kind), actually adequate for bioinformatics? For one thing, a hacker can certainly break the protective firewall of a bioinformatic server containing a large amount of personal data. Does it matter that these data are genetic codes of the members of the population, or just their credit card numbers and their names? I think it does because in a way genetic information is part and parcel of our very identity in a way that credit card numbers are not. After all, if our genetic information changes, then *we* change, but if our credit card numbers change, then nothing about ourselves does change. The genetic information defines the identity of our bodies and our mental characteristics. This makes it much more serious to steal genetic information than to steal credit card numbers.

Thus, if we follow Moor's logic, then there seems to be something inherently different about stealing someone's genetic data than merely external data like credit card numbers, and hence this calls for a special set of vocabularies that enable one to deliberate effectively about these newer issues. However, as bioinformatics also deals with matters in biotechnology and the life sciences, such as the fact that data obtained through bioinformatic techniques are crucial in developing tailor-made drugs that focus on specific individuals or types of individuals, thinking systematically about it also requires techniques already developed in bioethics and related disciplines such as political and social philosophy.

So it appears that the emerging ethics of bioinformatics is an amalgam of the two major strands of applied ethics. It remains to be seen how this new field actually turns out. What is clear, though, is that it cannot but employ the tools and techniques that are already developed in both computer ethics and bioethics. And finally what we learn from this is, then, that disciplines such as applied ethics, bioethics, computer ethics and so on are not ones whose boundaries are set objectively. It is true that these fields of inquiry are defined through their subject matter, but as the subject matter itself does change and many subject matters do fuse together, then these fields should also fuse together. Bioethicists, as well as computer ethicists, traditionally two separate groups of people, are finding themselves closer to each other than before.[6]

Endnotes

[1] Moor (2000).
[2] Moor (2000) pp. 24-25.
[3] Hongladarom (Forthcoming b).
[4] Moor (2000) pp. 25.
[5] Moor (2000); Hongladarom, (Forthcoming a).
[6] Research for this article was partially supported by a grant from the Thailand Research Fund. I am also indebted to Leonardo de Castro for his encouragement and support.

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The Moral Status of the Human Embryo in Chinese Stem Cell Research

Yanguang Wang*

Abstract: In January 2004, the long-expected "Ethical Guidelines for Research on Human Embryonic Stem Cells" was jointly released by the Ministry of Science and Technology and the Ministry of Health, Beijing, China. In "Ethical Guidelines for Research on Human Embryonic Stem Cells", Article 5 says, "The human embryonic stem cells used for research can be derived from: (1) spare gametes or blastula remaining after *in vitro* fertilization (IVF); (2) fetal cells after natural or voluntarily selective abortion;(3) blastula or monosexual split blastula by somatic cell nucleus transfer technique; and (4) germ cells voluntarily donated. Article 6 says, any blastula obtained by IVF, somatic cell nucleus transfer technique, mono-sexual reproduction technique or genetic modification cannot be cultured in *ex vivo* for longer than 14 days, since fertilization or nucleus transfer.

The support given in the guidelines for embryo research using somatic cell nucleus transfer technique, and support for human embryonic stem cell research under the condition of the embryo researched within 14 days, are facing objections from both China and some foreign countries. Also the support for the embryo research using spare gametes or blastula remaining after IVF; as well as for use of fetal cells after natural or voluntarily selective abortion is a subject of similar concern.

In my paper, I discuss the moral status of an embryo around 14 days old. I argue that an embryo within 14 days is not a person, an embryo is only a human biological life. While a human embryo has a certain value and it deserves due respect, if there are sufficient reasons it can be used. In the caseof the blastulas or mono-sexual split blastulas by somatic cell nucleus transfer technique, this is an ethical issue of creating embryos for research. I argue that because the researched Human Embryo is not a person, Kants' theory is not applicable here.

Keywords: *Ethical Guidelines, Human Embryonic Stem Cells, Chinese Stance.*

Chinese Stance and Ethical Debates on Source of Stem Cell Research

In January 2004, the long-expected writing "Ethical Guidelines for Research on Human Embryonic Stem Cells" was jointly released by the

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Ministry of Science and Technology and the Ministry of Health, Beijing, China. In 'Ethical Guidelines for Research on Human Embryonic Stem Cells', Article 5 states: The human embryonic stem cells used for research can be derived from (1) spare gametes or blastula remaining after *in vitro* fertilization (IVF); (2) fetal cells after natural or voluntarily selective abortion; (3) blastula or mono-sexual split blastula by somatic cell nucleus transfer technique; and (4) germ cells voluntarily donated. Article 6 says: any blastula obtained by IVF, somatic cell nucleus transfer technique, mono-sexual reproduction technique or genetic modification cannot be cultured in *ex vivo* for longer than 14 days, since fertilization or nucleus transfer.

The Guidelines certainly brings China even closer to the international community of life scientists, by providing clear standards for research; it also enables China to clarify its stance on human cloning in the international scientific and ethical fields. Since the Guidelines were reported in the mass media, these have played conceivable role in the international discussions, in the aftermath of clone reports from other countries, "Guidelines for research on human embryonic stem cells" codified the interpretation and reconfirmed some previous ethical and political statements, and shows that serious attention was paid to these issues in China as well. In my paper, I focus mainly on the Chinese stance on the source of human embryonic stem cell used for research, and present arguments regarding the moral status and respect for the human embryo within 14 days in the human embryo

The support given in the Guidelines for embryo research using somatic cell nucleus transfer technique, and for human embryonic stem cell (HES) research under the condition of the embryo researched within 14 days, are facing objections from both within China and some foreign countries. Also the support for the embryo research using spare gametes or blastula remaining after IVF; as well as for use of fetal cells after natural or voluntarily selective abortion are matters of similar concern. There are ethical arguments on the four sources of human embryonic stem cells.

Christians believe that life is sacred, and it is God's creation, and that creation begins at conception. Many believe that no scientist or person can define the official day when life begins on the basis of physical progression. To separate a spirit from a physical body (in other words, to say that something is not "alive" yet) is something best left to God's hands. They think that such research is touching upon a very controversial issue.

The Catholic Church and Right to Life organizations in Australia have taken an oppositional stance to the creation of embryos by the techniques for research. They hold that this is the same as dismembering embryos, embryo farming, and cannibalizing embryos for their spare parts while still alive. Marcia Riordan of the Catholic Archdiocese of Melbourne said, "There is no need to kill some people to cure others".[1] In May 2002, at the Council of Australian Governments Conference, Prime Minister and State Premiers decided to legislate that Australia has adopted the most conservative of the defensible positions to only allow derivation of new ES cell from spare embryos but not from IVF or cloning, because there is no creation of embryos by IVF for research.

I have to mention the double standard used in Germany and USA in these years. The double standard is such that the US federal institutes observe one standard, but private institutes are permitted not to do so. German law prohibits embryo research and embryo cloning within the state, but permits importation of stem cells derived from human embryos outside the country. So some leading Chinese stem cell researchers were worried that if the embryo stem cell research is limited by government, the development of Chinese stem cell research will be severely restricted.

There are objections from a small group of scientists and scholars from China. They argue that HES cell research should be forbidden, because if human beings go against the natural law, human beings will be punished by nature. HES cell research violates human dignity and this is a big challenge to human life.

To the spared gametes or blastulas remaining after *in vitro* fertilization and the fetal cells after natural or voluntarily selective abortion, some western bioethicists said if artificial abortion is morally wrong, we are wrong to use the embryos, if we use them, the same as we support the artificial abortion, and it is wrong to research on the embryos and destroy them these after, because the embryos constitute a personhood.

To such sources of research, the ethical issue is not an issue of "destructive embryo research", it is an issue that the fate or cells from embryos which are already destroyed and the embryo is not a person. Some embryos are destined to die because some spare embryos were going to be discarded in the fist place. About the ethical issues on abortions, I need not discuss this more, because there are much more earlier abortion around the world, also there are some strong reasons for some earlier abortion. In China, some Chinese scholars who supported using embryos to do research within 14 days, even said that the object of embryo research is inconsistent with values implicit in society, because there are many abortions in the mainland of China[2]. Also, if opposition to the use of spare embryos from IVF is the same as real opposition to IVF, because frozen embryos could be destroyed, infertile couples were permitted to destroy unwanted embryos rather than to donate them to other couples. A comparison of human stem cell research with IVF would show that spare embryos were destroyed to bring a new life into existence. So there is no difference when human stem cell technology uses spared embryos to produce embryonic stem cells to save an already existing life. Thus it is wrong to say that preventing human stem cell research places a greater value on the lives of potential human beings than existing ones.

One ethical intuition that seems to motivate the discarded-created distinction in the blastulas or mono-sexual split blastulas by somatic cell nucleus transfer technique, is that whereas the act of creating an embryo for reproduction is respectful in a way that is commensurate with the moral status of embryos, the act of creating an embryo for research is not. Because the first class of embryo was brought into being under moral circumstances-because the intentions of its makers were moral-research on them is deemed acceptable. Because the second class of embryo was not brought into being under equally moral circumstances-the intentions of its makers were not equally respectable-research on them is deemed unacceptable[3].

To the blastulas or mono-sexual split blastulas by somatic cell nucleus transfer technique, this is an ethical issue of creating embryos for research. If the embryo is seen as a person as, according to Immanuel Kant's deontological view that a person (rational beings) ought always and only to be treated as an end and not as a means, it is wrong since such research on embryos is treating them as means. However, I think that very early embryos, which do not have even a rudimentary nervous system, have no sentience, cannot feel pain, be hurt, or made to suffer. Because an embryo is not a person, does not have regard for itself as an end, so it does not know others have treated it as a means, therefore, there is no harm perceived to the embryos. So that they have no claim to any moral consideration to them.

Because there are relationships, between human stem cell research and embryo research, to my view above, I have argued here that the embryo is not a person, and examine what is the embryo's moral status. So the main point here is to interpret the moral status of human embryos .if the embryo is a person, to destroy it after stem cell research is the same as to kill a person, which is immoral and should be forbidden. But if an embryo within 14 days is not a person, the limited (but appropriate) moral status for them is consistent with limited research on them.

Criterion Approaches for Analysing Moral Status of Human Embryo

The moral status of the embryo is a function of the intention of its maker. Two broad approaches have been taken in debates over the moral status of the human embryo. One approach begins by proposing some single criterion of moral personhood. Beings that meet this criterion are believed to merit full and equal moral respect; those that do not are either denied respect, or accorded a lesser status. A second approach is pluralistic. It sees moral respect and personhood as deriving not from one or even two criteria, but from a variety of different and interacting considerations[4].

A single criterion approach to analysing the moral status of the human embryo can lead to widely different conclusions. One view holds that the embryo is a person, a being meriting full and equal moral respect, from the moment of conception or fertilization because at this moment a unique diploid genotype comes into being. For those who hold this view, humanness, in a moral sense, is the possession of a distinctive human genetic identity.

Others arrive at this same conclusion of proposing some single criterion of moral personhood by emphasizing the significant increase in potential for development that accompanies the transition from gametes to embryo. Those who hold these views do not always specify what they mean by fertilization or conception, i.e., whether it is to be understood as egg penetration by the sperm, fusion of the membranes of the sperm and egg, pronuclei formation, syngamy (when chromosomes from the male and female gametes join), or the activation of zygotic genes, which in the human embryo occurs around the 4-to-8-cell stage. But all are agreed that the moment of fertilization/conception, however defined, is the crucial beginning of personhood.

Moral positions emphasizing the genetic identity or developmental potential offer a definitive standpoint on the status of the embryo but they create paradoxes in logic, and run counter to many widely-accepted practices, including the use of the intrauterine device and other contraceptive methods that work by preventing implantation. The equation of genetic diploid starting with personhood leads to a logical paradox because twinning and the aggregation of two or more morula-stage embryos can occur well after fertilization. The emphasis on potential for development raises, but does not answer, the question of how much potential is needed for moral respect. It also ignores the fact that even though developmental potential increases at conception, it remains relatively low at least until implantation. For example, it is estimated that approximately 60 per cent of conceptuses are spontaneously aborted in the first days and weeks of pregnancy. It is morally unconvincing to claim absolute inviolability for an organism with which nature itself is so prodigal.

Among other single–criterion approaches to personhood, several positions exist that come to a very different moral conclusion about the status of the preimplantation human embryo. One position bases full moral personhood on sentience-the ability to feel or to experience pain. A second view emphasizes the beginning of brain activity or brain function. A third position takes as a marker for the beginning of personhood certain well-developed cognitive features or abilities such as consciousness, reasoning ability, and the possession of the self-concept.

While these views can lead to different conclusions as to when personhood begins, all support the conclusion that the preimplantation embryo does not merit the same degree of moral protection given to children or adult human beings. The absence of a nervous system until after gastrulation or neurulation makes it certain that the preimplantation embryo cannot experience pain, has no brain activity, and is not conscious or self-aware[5].

Many philosophers have explained their standards of and compare their opinions about personhood. Philosopher Immanuel Kant's deontological views are that persons are rational beings, they ought always and only to be treated as ends and not as means. Comparing his opinions with embryo research, we find that an embryo is not a rational being. Philosopher Regan believes that most sentient human beings-including some who are not even potentially capable of rational moral agency-have full moral status, as do many nonhuman animals. Peter Singer maintains that "the comparable interests of all sentient beings be given equal weight in our moral deliberations." Comparing their opinions with embryo research, we know that an embryo around 14 days old has no sentience which a person possesses[6].

Philosopher Duns Scotus used a word to explain his philosophy of individuation. The term is 'common nature'. Common nature is essentially the basis of the definition of an entity-what all members of a particular class share in is indifferent either to being a particular individual or referring to all members of that particular class. Thus, it requires something else-an individualizing principle-to make it a particular being of this class.[7] I think the 'common nature' of persons should be a rational ability, so that comparing with persons, the embryos' common nature can be held to be 'a possibility to be rational'.

Feminist Nel Noddings holds that moral status is a function of the emotional relationship she calls *caring*. On this account, it is not necessary for a sentient being already to be part of any of our communities for us to have moral obligations toward it; it need only be possible for us to care for it, and for it to respond appropriately[8]. But we can see that an embryo before 14 days has no emotional relationship with others, and has no response to caring, so such caring ethics can not be used to interpret the moral status of human embryos.

From the biological science point of view, Professor Thomas A. Shannon states, "cells at zygote and blastomere stages are totipotent or pluripotent. That is, they are not yet differentiated or committed to the particular cells they will become in the body, hence their obvious desirability for stem cell research. However, the very structure of these cells, while conferring some biologic unity on the developing organism, also strongly suggests absence of a more critical ontological level of organization". [9]

What properties suffice to make something a person? That certain clusters of properties are sufficient is almost universally accepted among philosophers. Consider, for example, a being that possesses consciousness, has preferences, has conscious desires, has feelings, can experience pleasure and pain, has thoughts, is self-conscious, is capable of rational thought, has a sense of time, can remember its own past actions and mental status, can envisage a future for itself, has non-momentary interests involving a unification of desires over time, is capable of rational deliberation, can take moral considerations into account in choosing between possible actions, has traits of character that undergo change in a reasonably non-chaotic fashion, can interact socially with others and can communicate with others. Few would disagree that such an entity is a person, and posses all of those properties relevant with respect to such an entity namely person.[10]

A second broad approach to understanding how personhood and moral protectability are established is pluralistic. It does not focus on a single criterion of personhood, but emphasizes a variety of distinct, intersecting, and mutually supporting considerations. According to this view, the commencement of protectability is not an all or nothing matter, but results from a being's increasing possession of qualities that make respecting it more compelling.

Among the qualities considered under a pluralistic approach are those mentioned in single-criterion views: genetic uniqueness, potentiality for full development, sentience, brain activity, and degree of cognitive development. Other qualities often mentioned are human form, capacity for survival outside the mother's womb, and degree of relational presence. Although none of these qualities is by itself sufficient to establish personhood, their developing presence in an entity increases its moral status until, as some point, full and equal protectability is required.[11]

Time Limit for Human Embryo Research

An early embryo certainly is not a person after we make clear what we mean by personhood. But why do we use the embryo within 14 days, what are the reasons for this, is our concern. In the wide range of questions asked by western scholars who express disagreements in research on human embryonic stem cells, it is advisable to set a clear time limit which will address the concerns of those of us who fear a slippery slope and possible abuses, while permitting research that promises to be significant for medical and therapeutic progress, to answer the question why the embryo within 14 days can be researched. The choice of 14 days or the appearance of the primitive streak may appear arbitrary, but there is a significance to the primitive streak, since embryonic development is a gradual process. That the primitive streak appearance indicates that the embryo proper is beginning differentiation and development as an individual, has been widely discussed.

The consideration of this stage can go back to at least as far as the 1970 paper, "Fatal Development," by Andre Hellegers. Hellegers cited the anomalies in embryonic development, particularly the ability of early embryos to twin and of two or more morula-stage embryos to aggregate, to question whether the pre-primitive streak embryo has the status of an individual human being.

This question was explored in much greater detail a few years later by James J. Diamond. Diamond asserted that an individual human being couldn't exist before 14 days'gestation, when the primitive streak appears. Some of the discussion material and papers prepared for the USA Ethics Advisory Board presented a similar view, and persuaded members of that body to adopt a 14-day limit in their 1979 report.

Since that time, extensive discussion of the moral relevance of the primitive streak has appeared in both the scientific and the ethical literature. The Ethics Committee of the American Fertility Society recommends that human embryos be not maintained for research beyond 14 days. The Committee on Ethics of the American College of Obstetricians and Gynaecologists argues that the lesser moral status of the 'pre-primitive-streak embryo' permits research at that stage. The Canadian Royal Commission characterizes its choice of 14 days as a "morally acceptable compromise in a pluralistic society in which there are various views about the relative importance of different stages of embryo development". The pre-primitive-streak embryo permits research at that stage and is similar to UK's standard, which allows the creation of embryos from IVF and cloning before 14 days for ES cell research.

There is the possible moral relevance of the appearance of the primitive steak in relation to embryo status, for the following reasons: Before the appearance of the primitive streak the embryo has the capacity of twinning or becoming more than one distinct individual. Two or more cleavage-stage embryos or morulae can also recombine and form a single chimera. Apart from the distinction between the cells of the trophoblast and the inner cell mass, the cells are totipotent and have not yet differentiated into specific kinds of tissue. There is no neural tissue whatsoever before the appearance of the primitive streak, hence no possibility of any kind of sentience. Soon after the primitive streak appears, the process of neurulation or the development of the nervous system begins. The development of the nervous system includes the development of the brain and the specific structures, which underlie sentience and the ability to experience pleasure and pain.[12]

At the appearance of the primitive streak, the embryo proper is determined to be a distinct developing individual. Twinning of embryos and aggregation of two or more cleavage stage embryos are no longer possible. With the appearance of the primitive streak, the cells of the inner cell mass begin to differentiate into various types of tissues. The embryonic disc becomes a unified, organized, differentiating entity, the embryo proper, which develops continuously into the fetus and infant. The existence of a distinct individual is important to arguments for embryo status based on personal identity. The absence of developmental individuation before the primitive streak supports the claim that the embryo could not be a person before that time, while leaving open the question of personhood after formation of the primitive streak. These facts led some Chinese bioethicists to conclude that no individuated human organism exists before about 14 days after fertilization, when the primitive streak that will become the spinal cord of the embryo begins to form.[13]

The embryo that is 14 days old seems to be similar to a gamete, a sperm or an ovum. Few would support the view that each sperm and ovum should be accorded full human rights. Few persons would support the claim that a condom, or a tablet medicine to prevent conception, is a killer of sperm and ovum. The use of a spermcide kills millions of sperm; surely it would be absurd to speak of all of them as losing their lives or being deprived of their lives. This suggests that it is not biological life that matters, but rather conscious existence. Few persons would support that nature is a killer because she lets many sperms and ovum die instead of allowing conception. Evidence suggests that some deficiencies causing failure lie in the oocytes themselves (intrinsic defects), while others result from suboptimal culture conditions or uterine environment (extrinsic defects). In some cases, the oocytes may be defective because they have developed chromosomal abnormalities during their long resting period in the ovary. In others, the rapid terminal maturation induced by the hormonal hyper stimulation may cause the oocytes to be abnormal and to either fail to fertilize or to develop abnormally following fertilization. Comparing the above facts, we conclude that embryos can be used within 14 days in research with respect.

Moral Status of Human Embryo

Philosopher Mary Ann Warren alleges that those who claim human status for embryos confuse biological and moral humanity, failing to see that it is possible to be biologically human without being morally human, that is, a full-fledged member of the moral community. It is not genetic human beings who are members of the moral community, but persons. She then goes on to identify persons as beings who are conscious, self-conscious, thinking, possessed of the ability to use language, and so forth. Clearly, embryos do not have any of these characteristics, and therefore embryos are not people and do not have the moral status of persons.[14]

How can the embryo's moral status be established? Warren propounded seven interactive principles to be used as complementary criteria of moral status:

1. The respect for life principle: Living organisms are not to be killed or otherwise harmed without good reasons that do not violate principles 2-7.
2. The anticruelty principle: Sentient beings are not to be killed or subjected to pain or suffering unless there is no other feasible way

of furthering goals that are (a) consistent with principles 3-7; and (b) important to human beings or other entities that have a stronger moral status than could be based on sentience alone.

3. The agent's right principle: Moral agents have full and equal basic moral rights, including the rights to life and liberty.
4. The human rights principle: Within the limits of their own capacities and of principle 3, human beings who are capable of sentience but not of moral agency have the same moral rights as do moral agents.
5. The ecologic principle: Living things that are not moral agents, but that are important to the ecosystems of which they are part, have, within the limits of principles 1-4, a stronger moral status than could be based on their intrinsic properties alone; ecologically important entities that are not themselves alive, such as species and habitats, may legimately be accorded a stronger moral status than their intrinsic properties would indicate.
6. The inter-specific principle: Within the limits of principles 1-5, non human members of mixed social communities have a stronger moral status than could be based on their intrinsic properties alone.
7. The transitivity of respect principle: With in limits of principles1-6, and to the extent that is feasible and morally permissible, moral agents should respect one another's attributions of moral status.[15]

In seems to me, the anticruelty principle was made for sentient beings, such as animals. The agent's right principle was made for moral agents, such as reasonable persons. The human rights principle was made for human beings who are capable of sentience but not of moral agency, such as patients in a persistent vegetative state. The ecologic principle was made for living things that are not moral agents, but that are important to the ecosystems, such as insects. The respect for life principle suit within-14-days-old embryos, they are living organisms, and they have no consciousness, no sentience, no autonomy. A within-14-days-old embryo is only a biological human being, it is a cluster of cells without bones, organs of other traits. The moral status of the embryo/fetus is just as the respect for life principle says: Living organisms are not to be killed or otherwise harmed without good reasons that do not violate principles 2-7.

After weighing both pluralistic and single-criterion approaches to understanding how personhood and moral protectability are established, we can conclude that although the embryo within 14 days warrants serious moral consideration as a developing form of human life, it does not have the same moral status as infants or children. This is because of the absence of developmental individuation, the lack of even the possibility of sentience and most other qualities considered relevant to the moral status of persons, personhood, and the very high rate of nature mortality at this stage. The important human benefits research might achieve counsels for allowing embryo research to be conducted under stringent guidelines. Thus, some research on the human embryo within 14 days should proceed.

What are our good reasons for getting stem cells from the embryos before 14 days old and to destroy them after? We are aware of the benefit and value of ES cell research. Human embryonic stem cell research has great potential value in effectively treating various human diseases, maintaining and promoting human health, it is good for hundreds and thousands of patients, families and society. Therapeutic cloning is a potentially important area of research, particularly with regard to circumventing the problem of rejection of cell or tissue grafts. To the public in China, they thought a sufficient reason was that human embryonic stem cell research has potential value in treating various human diseases and relieving millions of people's sufferings. In balance, priority should be given to millions of patients' health and life, so this research using embryo within 14 days should be permitted and supported. Also the Confucianist ethical explanations of 'Ren' means loving people, caring for others, caring for the patient. 'Ren' is an extension of the natural compassion that everyone feels in view of the hardship and misfortune of others.

Respect for Embryos in Stem Cell Research

Even though we balance important issues regarding the health and safety of women, children, and men against the moral respect due the human embryo within-14-days, given the conclusions about the moral status of the human embryo within-14-days, we can conclude that the health needs of women, children, and men must be given priority. However, the embryo merits respect as a developing form of human life and should be used in research only for the most serious and compelling reasons. Research involving human embryos should be limited to the shortest time period and should not be permitted beyond the time of the usual appearance of the primitive streak (14 days) *in vivo*. The number of embryos required for the research must be kept to the minimum consistent with scientific criteria for validity.

The selection of sources of embryos for the research must show respect for the special qualities of the human gamete and embryo. Because the embryo within 14 days possesses qualities requiring moral respect, research involving the *ex utero* human embryo within 14 days must be carefully regulated and consistently monitored. What made our Chinese bioethicsts thinking valuable and worthy of respect are the embryos. Even though the moral status of an embryo before about 14 days after fertilization is limited and smaller, it still worthy of respect.

We regard it as an important duty in the field of stem cell research. We worry that immoral attitudes and actions will prevail when scientists do stem cell research. According to the accepted Confucian view, the Chinese believe that personhood begins with birth. A person is an entity that has a body or shape and psyche, and has rational, emotional and social-relational capacities. So a human embryo is not a person, a personal life. Destroying an embryo as well as an abortion should not be taken as killing a person. However, a human embryo is a human biological life, not merely stuff like placenta. So it deserves due respect.

The ethical issues on the source of human embryonic stem cells in China are, how to respect the embryos and to protect the donors, and how to execute the principle of informed consent in the Chinese clinics. We have no exact statistical figures about abortion rates, but for sure there were many abortion cases in mainland China. The physicians could get the cadaver fetal tissue without the mother's informed consent in some places, and the physicians could also use the frozen embryos or gametes remaining after IVF without the mother's informed consent in some places during past years. Such a situation should be forbidden and we should respect to biological human life and early embryos or embryonic tissue, even though we think they can be researched on.

An embryo within-14-days is only a human biological life, but a human embryo has a certain value, it deserves respect. Destructive embryo research should only be approved in exceptional circumstances. Giving a moral status to embryos involves not whether we think we should do research with embryos, but how we think we should respect them, which is a function of what we think they are. For example, we think we can consistently accord cadavers the due respect and allow medical students under carefully circumscribed conditions to dismember them. Even though the embryo before development of the primitive steak, around 14 days after fertilization, it does not count as a person, but it is entitled to respect. What criteria are offered? The criteria are their possession of qualities that have value and potential good for research. Respect for an embryo does not mean that it can never be destroyed.

Is it meaningful to speak of respecting embryos? Philosophers Downie and Telfer maintain that respect for persons includes both an attitude and a moral norm. As an attitude, it implies thinking that something is valuable or estimable. Having respect implies that the thing should be cherished. As a moral norm, it means treating a person as an end and not merely as a means.[16] For Kant, self-determination was also coupled with ability to govern our conduct by rules, and it is this rule-giving and rule-governed behaviour that most clearly distinguished those deserving of respect. The embryo can be considered to have value, it can be cherished but it is not a person, so Kant's words that a person must be treated not simply as a means to someone else's end appears not to fit the case of the early embryo. But that the early embryo is a thing that should be cherished is right.

How do we respect non-persons? Philosopher Karen Lebacqz looked up Webster's New Dictionary 1979, The term 'respect' comes from the Latin *'re-specere'*, to look back at or to look again. To have respect is to take a second look, seeing below the surface to find the hidden value.[17] A review of this meaning of respect might apply to embryos, for embryos have hidden value, they can show honour and esteem.

How do we respect sentient beings? Philosopher Telfer and Downie appear to base their argument not on rights but on duties. When it comes to animals, the duty to avoid unnecessary suffering arises out of respect for them not as persons, but as sentient beings, because sentience is the basis for the development of distinctive aspects of personhood such as self-determination and thus it may provide the basis of respect for those who are not fully persons.[18] The embryos may not be fully persons, but they have the basis for the development of distinctive aspects of personhood, so they deserve due respect.

How do we have respect for plants? Barbara McClintock got an insight from her work with plants. She attended to the individual nature of every corn plant, never trying to force them into a mold. She expected the unexpected: she was open to the possibility that plants operated out of rules that were not known and understood by humans.[19] So respect for life (whether plant or embryo) more generally might require respect for the ways of other beings.

When dealing with the environment, nature, or creation, Karen Lebacqz thought two fundamental tenets appear to be at stake within ecological ethics. First, is the affirmation of the independent value of other creatures and of the ecosystem itself. Second, is to understand the interconnection and mutual interdependence of creation, including humans. Such respect implies seeing the intrinsic value of the other, a value on a larger perspective or on the role of that creature in the entire system.[20] What are the implications of these conclusions for respect for early embryos? Seeing its life as intrinsically intertwined with our own lives honours the value of the embryo.

Respect for the dead is a moral value in virtually every culture. It is called an intrinsic value. That is the value of respecting the dead is independent of what people happen to enjoy or want or need or of what is good for them. Philosopher Ronald Dworkin suggests that great paintings, wilderness areas, human cultures, languages, some species, traditional crafts, and human life itself all have intrinsic value. Respect for the dead also seems to fall into this category. If a culture lacked respect for its dead (had no death rituals, for example) we would probably regard it as considerably less evolved, even not quite human. During or after the research, embryos, as much as dead bodies, are a "potent symbol of human life and for that reason have moral value and deserve respect, even though they lack interests, rights".[21]

How do we respect embryos within-14-days in stem cell research? What does respect for embryos require? Respect sees a value in embryos beyond usefulness. The embryos should not be used cavalierly. The embryos are treated as an entity with incredible value; as something precious that cannot be replaced by any other blastocyst, whose existence is to be celebrated, and whose loss is to be grieved. Embryos can be used and can even be killed, to do so is not in itself disrespectful. The fact it can be used and killed does not mean that moral duties no longer hold. It may be permissible to do harm in order to do good, but the harms must be minimized. The fact that an embryo will be used in research does not mean that it is being devalued and disrespected, just as some Chinese medical students show respect by blessing of the spirits before dismembering the animal or human cadavers. In research practice, we can show respect toward embryos by carefully weighing the necessity of using them. We should undertake our daily routines in prayerful, respectful, grateful mode toward embryos in the developing Chinese Society.[22]

Conclusions

There are a few Chinese government administrative documents related to human stem cell, cloning or human embryo research in general namely "Procedures on Safety of Gene Engineering" issued by the Ministry of Science & Technology, China, 1993; "Procedures of the Administration on IVF Technology" issued by Ministry of Health, China, 2001; "Procedures of the Administration on Sperm Bank" issued by Ministry of Health, China, 2001. In order to protect the donor sources of human embryonic stem cells, surveys should be done to the units engaged in human stem cell research and the current practice of IVF in China. We have to know where did these researchers and others get the biomaterial from? Were they taken from IVF clinics, from early abortions, or donated by women with informed consent? Who was in charge of obtaining the material (researchers themselves, IVF clinicians, other parties)? Are they deliberately causing pregnancy for deriving stem cells? Controlling of abortion of donors or methods, and timing of artificial abortion by any means should be prohibited. The voluntary donation of reproductive cells should be done without economic compensation.

We hope the Ethical Guidelines issued by Chinese Ministries can be operational and meaningful for controlling stem cell research in China. Because the Ethical Guidelines are not a law, they have no legal force, but as a regulation, they could have the power to force scientists to follow them. But if there is no punishment, and there are no bioethicists within the Ethical Committee, the guidelines and requirements can only create a moral pressure on scientists. In the face of the rapid development of stem cell research in China, we bioethicists call for the researchers to follow the 'Ethical Guideline'. We hope the Ministry of Science and Technology, and the Ministry of Health of China could work out quickly how to revise the guideline, how to plan setting up the central and unit IRB, and how to train IRB members ethically. The most important thing is how this 'Ethical Guidelines for Research on Human Embryonic Stem Cells' is implemented in detail.

Endnotes

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[3] Erik Parens (2002).
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The Rise and Fall of Embryonic Stem Cell Research in Korea

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Abstract: The recent Hwang Woo-Suk scandal in stem cell research ranks among one of the biggest considering its scope and impact. In 2004, Hwang surprised the world by establishing a stem cell line from a cloned blastocyst. Another breakthrough in the following year constited in making the patient-specific embryonic stem cells which made him rise to international stardom.

It is not true that there was no ethical backlash to Hwang's research. The Catholic Church, NGOs and bioethicists were outspoken critics of Hwang from the outset.

The Korean government should bear the main responsibility for the Hwang scandal. Distortion and exaggeration in the reports of the irresponsible media aggravated the situation.

Scientism and crude nationalism are also to be blamed. Asia has a deep-rooted tradition of scientism which has lasted for more than a century. In the nineteenth century Asia was overrun by Western imperialism. Asian countries had to make desperate attempts to survive the challenge. After the liberation in 1945, "nation building with science and technology" has been the national motto of Korea. Scientism continues to be paramount in Korea

Keywords: Alliance of Science and Technology, Embryonic Cloning, Ethics Solidarity, Nationalism, Research Ethics, Scientism, Stem Cell.

In the history of science, frauds and fakes are not rare. However, the recent Hwang Woo-Suk scandal in stem cell research is one of the biggest considering its scope and impact. The collapse of research ethics in Korean biotechnology has dealt a fatal blow not only to Korea, but also raised many issues of debate for the whole world. The Hwang scandal is too complex to be analyzed intensively in a short paper. This paper tries to highlight some major issues of stem cell research in Korea.

The birth of Dolly in 1997 aroused great concern among the Koreans. That year more than ten academic meetings were held to discuss the meaning and impact of animal cloning. Hwang Woo-Suk,

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a veterinarian appeared suddenly at the centre of reproductive technology.[1] Scientists by and large were excited, while humanists and social scientists were somewhat sceptical. If animals could be cloned, it was probable that human cloning would be realized eventually. Many people talked about the necessity of a National Commission on Bioethics. As 'cowboy cloners'[2] did sensitive researches with embryos, the pressure to regulate them was mounting. In 2000, the Ministry of Science and Technology (MOST) created the Bioethics Advisory Commission (KBAC) to make policy recommendations on human cloning and stem cell research. While China and Japan were framing guidelines on stem cell research, Korea went forward with legislation.[3] The primary task for KBAC was to draft the Bioethics Law. KBAC consisted of 20 members: 10 scientists (biotechnology and medicine) and 10 non-scientists (philosophy, social sciences, NGOs and religion). It existed for only one year.

KBAC could complete the framework of the 'Basic Law on Bioethics' after meeting 13 times for 7 months. The recommendations of KBAC to MOST were for instance: i) to prohibit both reproductive and therapeutic cloning, and ii) to allow temporarily stem cell research on the surplus frozen embryos created through *in vitro* fertilization (IVF). It was an unexpected result of the dramatic compromise between scientists and non-scientists. Neither conservatives nor liberals were satisfied with the compromise. The recommendations should have been respected as promised at the beginning, but MOST obviously did not like them. As a result MOST failed to submit its own version of the bioethics law to the National Assembly.

After one year, the Ministry of Health and Welfare (MHW) took over the bioethics issue, which MOST had been responsible for. Unlike MOST, the MHW took a position similar to the recommendations by KBAC. MHW in cooperation with Kim Hong Shin, a member of the National Assembly, submitted a bill entitled 'Bioethics and Biosafety Law.' Later, Lee Sang Hee, another member of the National Assembly and former Minister of Science and Technology submitted a different bill entitled 'Prohibiting Human Cloning and Stem Cell Research Law.' This bill strongly supported embryonic stem cell research.

The preparation of the bill on the government side dragged on for more than three years. At the end of 2003, the adjusted bill was passed by the National Assembly. The result was that the final bill became very much like Lee's proposed bill. This meant the victory of the growth-oriented MOST. The degraded bill caused a furious reaction from civil movement groups. The important points in the 'Bioethics and Biosafety Act' were twofold. First, human embryonic cloning was permitted in case it was approved by the Stem Cell Research Committee. Second, and more serious was that the bill could be interpreted to allow research where a genetic mix between humans and animals takes place.[4] The 'Bioethics and Biosafety Act' was to come into force from 2005 after one year of deferment. It is believed that the Act was made meticulously to protect Hwang Woo-Suk. If the Korean government had taken the recommendations of the Bioethics Advisory Commission, the Hwang scandal could not have happened.

In 2004, Hwang surprised the world by establishing a stem cell line from a cloned blastocyst. Another breakthrough in the following year consisted in making the patient-specific embryonic stem cells which made him rise to international stardom. It was also the fruit of the deliberate operation of the Korean government to make him a national hero. But for the massive support of major media in Korea, it would have been impossible for him to be a god-like figure among the people. After the 2004 paper of Hwang et al. was published in *Science,* a further recognition was waiting for him. He was made a 'Supreme Scientist' with special guards provided by the government. No Nobel Prize winner has ever had such honours as Hwang enjoyed. The Korean Air gave him two first class tickets for ten years. In October 2005, Hwang was at the peak of his career when he opened the World Stem Cell Hub with President Roh Moo-Hyun and Ian Wilmut. Then, he fell abruptly.

In Korea though the main concern was with human cloning; it moved to embryonic cloning subsequently. Numerous papers on cloning appeared in philosophy journals; most of them against human cloning, but there were some favourable responses to it. The Korean National Commission for UNESCO organized a consensus conference on cloning, which reached a conclusion not only against reproductive cloning but also against embryonic cloning. The Korean media, however, failed to turn the discussions into public debate; as their objective was merely to target for Hwang Woo-Suk. There have been no debates on cloning in the true sense of the word. In the case of Korea, the socio-political context was much more important than the perspective from philosophy or religion in the problem of stem cell research. One-third of South Koreans are Christians. However, the idea that life belongs to the realm of God does not matter very much to them. In other words, religious affiliation has little to do with bioethics in Korea.[5]

Contrary to the common belief outside of Korea, it is not true that there was no ethical backlash to Hwang's research. The Catholic Church, NGOs and bioethicists were outspoken critics of Hwang from the outset. Right after the 2004 paper came out, the Korean Bioethics Association (KBA) formed the 'Ad Hoc Committee on the Research Ethics of Therapeutic Embryonic Cloning.' KBA sent a letter to the editor of *Science* concerning the problem of the Ethics Committee.[6] The letter was published with Hwang's response more than half a year later. At the General Meeting in May, KBA adopted a statement challenging Hwang to have an open discussion on the ethical problems of his research: IRB, authorship and acquisition of eggs.[7] The problem of authorship was raised by Lee Pil Ryul, Professor at Korea National Open University and the Centre for Democracy in Science and Technology, an NGO; and, the egg problem by David Cyranoski *Nature*'s correspondent in Tokyo, respectively.[8] The request was ignored by Hwang, though he admitted that he had some ethical problems on other occasions. The indifference to ethics on the part of the government and media also helped Hwang's arrogance.

Gerald Schatten's sudden severance of the relation with Hwang was a turning point for the decline of Hwang. It brought out the charges of oocyte donation irregularities by *Nature* anew. It was not until the 'PD Notebook' of MBC (Munhwa Broadcasting Corporation) television raised questions about the research that Hwang confessed his wrong-doing in obtaining the eggs. All the ethical suspicions regarding his paper turned out to be true. The verification efforts of young scientists through BRIC (Biological Research Information Centre) and the prompt investigation by Seoul National University further concluded that both the papers by Hwang were nothing but fakes. It was shocking news even to the critics of Hwang. The two papers by Hwang published in *Science* were retracted. Hwang was fired from Seoul National University after a long deliberation. The Korean Society for Molecular and Cell Biology expelled him and the Ministry of Health and Welfare removed his license to conduct embryonic stem cell research. The Ministry of Science and Technology stripped him of the title 'Supreme Scientist.' Intensive investigations by prosecutors followed and the trial is going on. Investigations by the National Assembly agreed to by major parties have not yet been carried out. Hwang still holds some important honorary posts including the membership of the Korean Academy of Science and Technology (KAST) and the Board of the Korean Federation of Science and Technology Societies (KOFST). There is no doubt that Korean society is too magnanimous to him. The case is yet to be concluded in the midst of continuing resistance offered by the fanatic supporters of Hwang.

The Korean government should bear the main responsibility for the Hwang scandal. Its growth-first policy in developing biotechnology left no room for any kind of regulations or criticisms. All Asian countries are keenly interested in developing biotechnology; Korea, however, dashed ahead recklessly and the result was a debacle. President Roh Moo-Hyun with his entourage gave huge support to Hwang, while all the political circle leaders except the Democratic Labour Party praised Hwang as a hope for the nation. But no one has apologized for the awful misjudgement. Distortion and exaggeration in the reports of the irresponsible media aggravated the situation. There was no place for ethics in the hostile landscape dominated by the government and media.

Scientism and crude nationalism are also to be blamed. Asia has a deep-rooted tradition of scientism which lasted for more than a century. In the nineteenth century Asia was overrun by Western imperialism. Asian countries had to make desperate attempts to survive the challenge. In Japan it was believed that the only way for survival was to catch up with Western science and technology. Of Tokyo University graduates in the 1890s 85 per cent were science and engineering majors. Japan became the first country in Asia which succeeded in modernization. There were similar aspirations for science and technology in both China and Korea, though in these two countries there was more resistance by traditionalists. It was hard for China to attain modernization even after the revolution of 1911. Korea lost the last chance and became a victim of Japanese imperialism in 1910. In Korea under colonial rule, there was a belief that independence could be achieved through science and technology. The nationwide science movement in the 1930s is a good example. After liberation in 1945, 'nation building with science and technology' has been the national motto of Korea.[9]

Korea emerged as an economic giant from a poverty-stricken country in the 1960s. During a period of 45 years the national income per capita rose from $200 to $17,000. But the amazing success in industrialization was possible only at the expense of the environment, tradition, and ethics. Science and technology was the handmaiden of the economy. It was only 10 years ago that the Korean government began to consider science and technology as culture also. Nevertheless, scientism continues to be paramount in Korea. Both the government and opposition are growth-oriented and they are supported by the major mass media groups. The government has been extraordinarily interested in developing biotechnology. In 1983 it framed the world's first the Law for the Promotion of Biotechnology in the world. Even the National Human Rights Commission of Korea, which had opposed the dispatch of Korean troops to Iraq, remained silent concerning the misconduct of Hwang. The situation in Korea until November 2005 was something like the United States right after September 11.

Korea had good reasons to be nationalistic. There had been ceaseless invasions from its neighbours. It is still said to be an ant surrounded by four elephants. It suffered from Japanese colonial rule for 35 years. After 1945, it was continuously humiliated by the four big powers surrounding the peninsula. Korea is now the twelfth economic power in the world. It is not as friendly with the United States as it used to be. In a climate of the growing nationalism of Japan and China the majority of Koreans are still nationalists or patriots. Hwang exploited the nationalist feeling of people shrewdly. He kept paraphrasing Pasteur's famous words: "There is no national border in science, but a scientist has a fatherland." When he came home after reading his paper, he said proudly: "I have fixed our national flag in the heart of the United States." Some politicians and journalists joined him in instigating patriotism.

It is held that the Hwang scandal was a confrontation between the 'Alliance of Science and Technology'[10] and the 'Solidarity of Ethics.'

The former consisted of scientists, government, business and media which were united with vested interests and ideologies. The latter was composed of NGOs, religious groups and bioethicists. A formal alliance never existed, but the de facto alliance was extremely powerful. An alliance on such a scale is unprecedented in Korean history. There were formal solidarities for several campaigns in different forms, but they were heterogeneous, loose and hence weak. Only the Catholic Church and some conservative Protestants among religious groups were critical of Hwang. Feminist and environmental NGOs did not cooperate actively with the Centre for Democracy in Science and Technology, which alone fought against the 'Alliance' consistently. "South Korea's handful of bioethicists had no leverage".[11] The defeat of the 'Solidarity' by the 'Alliance' was too natural, since these two were incomparable.

After Hwang was dishonoured, the main issue now becomes research ethics. The government is hurriedly drafting a guideline for research ethics. Of course, research integrity is important, but due to an over-emphasis on this, other ethical problems of stem cell research are blurred. There have been many conferences dealing with various problems of the Hwang scandal in a broader context. There was a session on 'What does the Korean Stem Cell Scandal Imply to STS?' at the EASST 2006 in Lausanne. Four sessions are being organized in the upcoming 4S conference in Vancouver. It is a real challenge to history and the philosophy of science and STS. There are also campaigns for making a 'Code of Conduct for Scientists and Engineers'[12] and for strengthening bioethics education. However, it is to be regretted that neither the government nor media is interested in them.

One of the early issues of Hwang's research was to do with eggs. Many Westerners find it difficult to understand the indifference of the Koreans to the problem of eggs. How could Hwang get over two thousand eggs so easily? They tend to consider that it is due to cultural difference, but it is not that simple. Korea was tremendously influenced by Confucianism, which is profoundly ethical. Confucianism was the guiding principle of the last dynasty in Korea for 500 years. According to the Confucian ethics, all parts of the body are important, since they are from the parents. The negligence of ethics is quite a new phenomenon resulting from the civil war and industrialization. In the 1950s, the Korean government launched a successful campaign for birth control. Thus, abortion became a common practice in Korea, though it was against criminal law. It seems that the negligence of life has something to do with the 'paradise for abortion.' It was disgusting to see thousands of Korean women including some members of the National Assembly volunteer to donate eggs to Hwang. Hwang's misconduct in acquiring eggs is no less serious than his fraud in research. It is vital for the Koreans to restore the respect for life. Extensive discussions on this problem are necessary.

Korea is suffering from its failure to liquidate the past properly. The Japanese colonial rule, the Korean War, two military dictatorships, the Kwangju massacre have never been concluded. They are still a cause of quite a few problems. This is why the Hwang scandal should be finalized neatly; if the Koreans fail to do so, there is no guarantee that there will not be a second Hwang. There are many lessons we should learn from the Hwang scandal. According to two Austrian political scientists, the imprudent fraud of Hwang is a result of political irresponsibility.[13] "Korea should provide the system of science with clear structure of political-administrative responsibility, transparent decision processes and the room and chance for scientific criticism." Cho, a Korean-American bioethicist, concludes: "The lesson to be learned is that we need to do a better job of holding research institutions accountable for setting up systems and mentorship that will produce integrity in its scientists."[14] But the most important lesson is that we came to rethink what science really is and where science should go.

Endnotes

[1] Kim G.B. (2006).
[2] Rose, Hilary (2004).
[3] Lee & Yamazaki (2003); Wang (2003).
[4] Cf. Han *et al.* (2003); Pak U. J. (2005), Ch. 8.
[5] Cf. Song (1999).
[6] Song (2004)
[7] Koo (2005).
[8] Lee P. R. (2006); Cyranoski (2006b).
[9] Song (2006a).
[10] Chang (2005), Kim J. Y. (2006).
[11] Editorial, *Nature* (2005).
[12] Song (2006c).
[13] Gottweis & Triendl (2006).
[14] Cho *et al.* (2006).

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AsianBio2006

Third Asian Biotechnology Conference
09-10 November 2006, Diamond Hotel, Manila, Philippines

Proceedings of the Conference[1]

When public and private institutions work hand in hand with government regulators, modern biotechnology can effectively address concerns regarding health, agriculture and the environment in a socially acceptable fashion. This, however, comes with a caveat. The biotech train is not out to the woods yet. There are many stones left unturned. There is still much to be done. This became apparent at the Third Asian Biotechnology Conference held at the Diamond Hotel in Manila, the Philippines, which saw participation of 220 people from Australia, India, Indonesia, Italy, Myanmar, the Philippines, Singapore and the United States.

The theme of the conference was "Biotechnology Opportunities for Developing Countries". The formal conference started off with Dr. Edgar DaSilva reading a backgrounder on Asian Biotechnology Conferences written by Dr. Nagesh Kumar, Director General of Research and Information System for Developing Countries (RIS). The series was started by RIS and the first two Asian Biotechnology Conferences were held under the aegis of RIS in India. At the end of the backgrounder, Dr. DaSilva requested the Secretary of Department of Science and Technology to unveil special issue of RIS publication, *Asian Biotechnology and Development Review*. The special issue focussed on "Bioethics in Asia". In his welcome message, Dr. William Padolina, Deputy Director-General of the International Rice Research Institute said that although we are making headway in biotechnology, we must not forget that we are confronted by legal, ethical political and commercial issues. These demand a high level of accountability and transparency. Dr. Hubert Gijzen gave an idea of UNESCO's interest in biotechnology. In her keynote speech, Department of Science and Technology Secretary Dr. Estrella Alabastro spoke on the growing importance of biotechnology all over the world. She pointed out that although the United States is presently the acknowledged leader in biotechnology, and that in 2005 the EU had the highest ever increase in biotechnology revenue growth, the Asia Pacific region showed the highest percentage revenue growth in biotechnology. Citing a UN report, she said that biotechnology offers unparalleled growth opportunities. With regard to success factors, she pointed out that information dissemination and partnerships at many levels are crucial for success in biotechnology endeavours.

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[1] Written by Ben Peczon, with comments provided by the participants.

Enabling policies are crucial for biotechnology initiatives to take off. Session chair on "World Perspectives on Bio-commercialization". Dr. Gurinder Shahi gave an overview of global trends and opportunities on bio business, a term he and his colleagues coined. He pointed out that keys to success in bio business are smart people, smart ideas, smart money and smart alliances. Although Asia is well placed to be a major player for value creation, the most difficult part of the success equation seems to be finding smart money, i.e., funding of start-ups before the rest recognizes the potential. Dr. S. R. Rao, Advisor to the Department of Biotechnology of India's Department of Biotechnology, who works day-to-day on creating value through biotechnology in India, presented and gave an evaluation of Indian policies and implementation strategies. He said that for policies to be effective, they must be backed up with coherent implementation strategies. Atty. Peter Tabor, International Economist, US Department of Agriculture, Foreign Agricultural Service described oversight of biotech crops in the United States. This oversight is based principally on the concept of substantial equivalence. Dr. Saturnina Halos presented the Philippine government policies which guide the science based approach in the utilization of biotech crops in the Philippines. Crucial to the Philippine system is the role of its Committee on Biosafety. The policies in place have permitted the Philippines to become the first country in Asia to commercially grow a biotech crop for food and feed, Bt. corn. Dr. Patricio Faylon, Executive Director, Philippine Council for Agriculture, Forestry and Natural Resources Research and Development of the

Department of Science and Technology presented enabling mechanisms for the promotion of agricultural biotechnology in the Philippines.

For all its potential, biotechnology must be utilized in a safe and responsible manner. Session Chair (On Essentail Issues) Dr. Edgar DaSilva pointed out the need for sustainable development emerging from use of ecologically sound, economically viable, socially just and culturally appropriate policies and practices. Although "biosafety" is not defined in the text of the Cartagena Protocol on Biosafety, Dr. Wendy Craig of the Biosafety Unit of the International Centre for Genetic Bioengineering and Biotechnology (ICGEB), presented a comprehensive set of questions to help assess the safety/risk of biotech crops. In addition, by giving a summary overview of biosafety policies around the world, she demonstrated how GMO labelling is likely to be the next battleground in the arena of international trade, and further, how ICGEB is providing assistance to developing countries in this and many other biosafety issues. A program to assist developing countries develop regulations and policy which are practical, workable, appropriate and science based involves the International Food Policy Research Institute, the Danforth Center, Michigan Sate University and Western Michigan University. Dr. Hector Quemada presented ongoing activities and challenges facing this Program for Biosafety Systems. In particular, one component, the Biotechnology/Biodiversity grants, generates data that should be useful for risk assessments in developing countries, but the design and interpretation of these experiments, as well as their impacts on regulatory policy, should be thoughtfully and judiciously applied. Pollution from oil spills, distillery wastes, landfill leachates, etc. must be addressed. Dr. Ernesto del Rosario and his colleagues at the University of the Philippines at Los Banos described potential solutions using biotechnology to address these problems.

Medical biotechnology took center stage in the session chaired by Dr. Jaime Montoya, Executive Director, Philippine Council for Health Research and Development. A huge percentage of the global gross national product is spent on health care. Citing 2001 figures, Dr. Gurinder Shahi presented numbers showing that globally, healthcare accounts for 9.1 per cent of GNP. Biotechnology claims an increasing percentage of this sector. But the growth is not in medical biotechnology alone. An optimist who sees a half full glass instead of a half empty glass, Dr. Shahi sees potential in many aspects of biotechnology. He sees the spinning off of agricultural biotechnology into pharmaceuticals, nutraceuticals, cosmeceuticals, specialty foods, industrial feedstocks, etc. To maximize potential he described a game plan whereby the objective is to create "summit opportunities" (high value products) from "cloud opportunities" (ideas which have not yet been converted to commercially viable products) rather than compete based on price alone in ubiquitous well known commodities. In the hunt for converting cloud opportunities into summit opportunities are Dr. Nina Gloriani Barzaga and her colleagues at the University of the Philippines and Nagoya City University Graduate School of Medical Sciences who are into creation of plant made pharmaceuticals. Dr. Barzaga described the group's ongoing quest to made edible vaccines to control Salmonella typhi, HIV and rabies. Also in the same hunt for summit opportunities is the group of Dr. Filipinas F. Natividad. Dr. Natividad quoted a 2002 report from the University of Toronto which lists molecular diagnostics as number one in approaches to improve health. She discussed the utility, advantages and disadvantages, and the regulatory approval process for molecular diagnostics and shared her group's experience while working on a polymerase chain reaction based test for the dengue virus. She also pointed out the huge growth potential in the use of molecular diagnostics in pharmacogenetics.

Two major issues, intellectual property rights and ethics were covered in the session on Enabling Issues run by Dr. Reynaldo Ebora, Executive Director, Philippine Council for Advanced Science and Technology Research and Development. Dr. Sachin Chaturvedi brought out major concerns regarding plant variety protection, patents, protection of traditional knowledge and folklore, access to biodiversity and benefit sharing. With respect to patents, there is concern that patents granted may be too broad. In some instances patents which cover research tools wield an extremely large influence on downstream products. With respect to seeds, Dr. Chaturvedi reported that seed firms in India find it difficult to access relevant genes as their sequences have been patented. Since licensing fees are not regulated and can be incredibly expensive, the combined lack of access to desired gene sequences and high licensing fees place constraints on wider utilization of the technology. With respect to biodiversity and benefit sharing, groups such as the Like-Minded Groups of Mega Diverse Countries

(LMMC) may need to pursue legally binding instruments at appropriate international fora.

The issues raised by Dr. Chaturvedi's presentation suggest that this area may need to be discussed in more detail at the Fourth Asian Biotechnology Conference, or at some earlier forum, if possible. In his presentation on Ethics, Bishop Jesus Varela said that the Second Vatican Council affirmed that man 'judges rightly by his intellect (that) he surpasses the material universe, for he shares in the light of the divine mind.' Moreover, Bishop Varela said that "for every human need, the ever creative mind would always come up with the appropriate technology to adequately respond." These statements are in support of the belief that human intervention in the work of God's creation is not a violation of God's Mandate. This does not give Man carte blanche to do anything he wants. Bishop Varela advocates use of "The Principle of Double Effect" and the "Precautionary Principle." According to the former principle, when both beneficial and harmful effects are foreseen, the following must hold:

1. The act must be morally good or at least neutral
2. The intention is to achieve the good effect and avoid as much as possible (best efforts) the harmful effect
3. The foreseen benefits must at least be equal if not be greater than the foreseen harm.
4. The beneficial effect must flow directly and immediately from the action and not as a result of the bad effect.

According to the Precautionary Principle, Bishop Valera said, "prudent policies, based on the Precautionary Principle require that decisions be based on a comparison of risks and benefits."

The session on "Advancement and Prospects in Agri-Biotechnology in Asia: Status and Priorities" was chaired by Dr. George Fuller, Executive Director, CropLife Asia. In the overview lead paper, Dr. Randy Hautea described the global trends in agri-biotechnology. In 2005, 220,000 million acres were planted to biotech crops, an 11 per cent increase over the 2004 acreage. Sixty three countries produce or performed research on 57 biotech crops. In the future, Dr. Hautea said that biotech crops introduced will be more tolerant of adverse agronomic conditions, be safer as food, have improved nutritional value, enhanced taste, better fiber and longer shelf lives, and will serve as platforms for plant-made products and renewable energy. The challenges enumerated for agri-biotechnology include:

1. Continuing responsible stewardship in risk assessment
2. Improving communication with society
3. Ensuring that biotech crops in conjunction with conventional technologies contribute to sustainable agriculture, alleviation of poverty and a safer environment.

The eggplant is an important crop in India, requiring 510,000 hectares to meet local demand. Losses of up to 50-70 per cent require from 25 to 70 insecticidal sprays for effective control of lepidopterans. Dr. Bharat Char, Mahyco Research Centre, Maharashtra Hybrid Seeds Co., Lt., of Jalna, India, described completed and ongoing work to meet regulatory requirements in ongoing efforts to bring Bt eggplant to commercial production. Dr. Jerry Flint, Director, Technical Development-Asia Pacific, Monsanto, described the history of Bt corn development and factors leading to its successful commercial deployment in the Philippines. Noteworthy are the results of an independent study which shows that Filipino farmers retain 52 per cent of value created. In the Philippines, 40 per cent of children from 6 months to 5 years old and 20 per cent of pregnant and lactating mothers are deficient in vitamin A. Predominantly a rice eating country, Filipinos would gain health benefits from consuming rice with built-in beta carotene, the precursor to vitamin A.. Dr. Rhodora R. Aldemita, Chief Science Research Specialist, Philippine Rice Research Institute at the Science City of Munoz, Nueva Ecija, the Philippines, who recently completed a postdoctoral stint at the Albert Ludwigs University at Freiburg, Germany, described the pioneering work of Ingo Potrykus and Peter Beyer in building in beta carotene into rice. She also described ongoing activities in meeting intellectual property concerns and increasing the beta carotene content of local rice varieties. The good new is that that by 2011, Filipino farmers may expect to be able to plant the so-called Golden Rice and, moreover, be able to replant the seeds. Drought is a major constraint in agriculture in many parts of the world. Dr. Kiran K. Sharma, of Genetic Tansformation Laboratory, International Crop

Research Institute for the Semi-Arid Tropics (ICRISAT), described completed and ongoing research at ICRISAT to alleviate poor production in drought susceptible areas. Dr. Dennis Gonsalves, Center Director, Pacific Basin Agricultural Research Center, Hawaii, related his success with papaya resistant to the papaya ring spot virus (PRSV) in Hawaii and his experience in transferring the technology to Thailand. In the district of Puna, on the big island of Hilo, in 1994, up to 95 per cent of the papaya stand was affected by the PRSV, creating a big problem for papaya growers. Fortunately, Dr. Gonsalves and his colleagues had been working on creating transgenic papaya reistant to PRSV since the mid 80s. From their accumulated knowledge, by 1999, the decimated papaya plantations had been successfully replanted with healthy papayas which were resistant to the PRSV. In 1997, Dr. Gonsalves brought transgenic papaya to Thailand. Field trials conducted in 1999 showed excellent resistance to the PRSV. Then the project got bogged down in meeting regulatory requirements. By 2001, Thai regulators placed a moratorium on "on farm" testing of transgenic plants. This moratorium was lifted briefly in 2004 but in August of that year, Greenpeace made a massive effort against transgenic papaya, stalling the project up to the present time. The lesson learned is that even with a willingness to meet regulatory requirements, a project can be stalled. The story of Dr. Gonsalves brings us back full circle to the message of Secretary Estrella Alabastro of the Philippine Department of Science and Technology that there is a need for dialogue with all stakeholders to see the completion of a project and the reminder of Dr. William Padolina that there are many issues to address with heightened vigilance. Everyone must pull together to see to it that the promise of biotechnology comes to fruition in a manner that meets the needs of all stakeholders.

Bio Web

Select Sites on BioEthics

Genome News Network

The Genome News Network (GNN) highlights primary sources available on the Web and links to a cademic centers and organizations that are exploring the possible consequences—both good and bad—of recent and future advances in technology. Genomics and new technologies are changing how biomedical research is done and will ultimately change the practice of medicine. GNN site is a guide to the primary materials in ethics in the US context which covers landmark documents, legislation, and religious views—that have shaped the field of bioethics and to the academic centers, organizations, and government agencies that, along with the public, will do so in the future.
http://www.genomenewsnetwork.org/resources/bioethics/index.php

Bioethics in Asia

This document site has selection of paper on different aspectof bioethics in the Asian context. It has country specific overviews and analysis of various religious approaches as well. Basically is collection of the Proceedings of the UNESCO Asian Bioethics Conference (ABC97) and the WHO-assisted Satellite Symposium on Medical Genetics Services, 3-8 Nov, 1997 in Kobe/Fukui, Japan; 3rd MURS Japan International Symposium; 2nd Congress of the Asian Association of Bioethics; 6th International Bioethics Seminar in Fukui Editors: Norio Fujiki, and Darryl R.J. Macer.
http://www2.unescobkk.org/eubios/abce.htm

Eighth Asian Bioethics Conference

The Asian Bioethics Conference (ABC), organized by the Asian Bioethics Association, started in 1997 with the aim of promoting the study of bioethics in Asia as well as to emphasize the important role that

bioethics in Asia plays in the global dialog on the topic. From its beginning in Japan, the Conference has been held in many countries in Asia, and the eighth one would be hosted by the Chulalongkorn University in Thailand on March 19 to 23, 2007.
http://www.stc.arts.chula.ac.th/ABC2007/

Center for Ethics of Science and Technology, Chulalongkorn University

The Center for Ethics of Science and Technology is a research unit based at the Faculty of Arts and supported by Chulalongkorn University in Thailand. It functions as a virtual center where faculties from various academic disciplines meet and work together. It aims at conduct research on various aspects of ethics of science and technology, most notably those related to information technology and biotechnology, as well as the relation between science and society.
http://www.stc.arts.chula.ac.th/index.html

University of Philippines: Training Programme

This unique initiative in Asia targets at the need to develop sufficient expertise in the region to manage ethical issues given the fact that health care systems and policies to meet the ever-growing need of populations in the Asia Pacific region are expanding. There is a need for personnel who have had relevant training in bioethics in institutions in the Philippines and neighboring countries. Some of those who are already involved in bioethics work may not be available for a long-term resident training program. The university designs a short non-degree training program.
www.bioethics-training.org

Bioethics Network in China

The purpose of establishing Bioethics Network in China is to report the major events in China's bioethics to the world. The idea is to address the misunderstanding or distortion about China's bioethics in the presentations or articles delivered.
http://www.chinaphs.org/bioethics/index.htm

BioMedical Ethics in India

The Indian Council of Medical Research (ICMR) is leading this initiative and proposes to provide ethical guidelines for animal related research

and also for the medical research. ICMR has also worked out broad guidelines for bioethics.
http://www.icmr.nic.in/bioethics.htm

Bioethics.com

This is a public service provided through the collaboration of many individuals and organizations to improve the discussion of issues in bioethics.
http://bioethicsnews.com/

University of Toronto Joint Centre for Bioethics (JCB)

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http://www.utoronto.ca/jcb/home/main.htm

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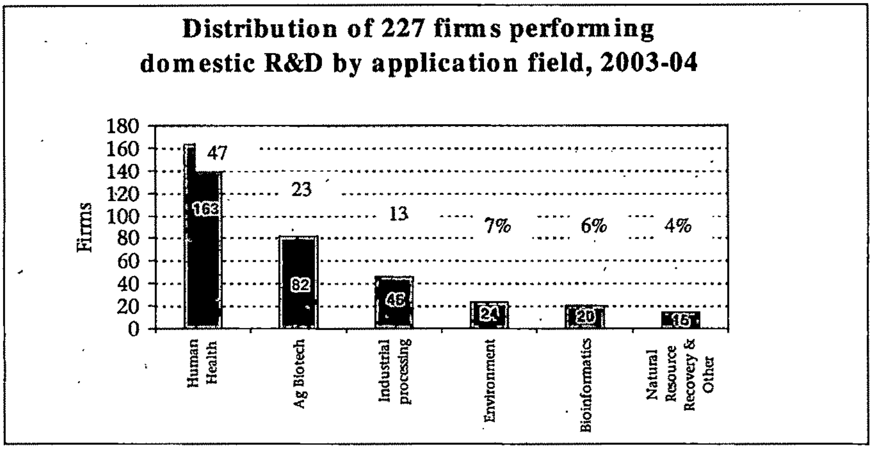
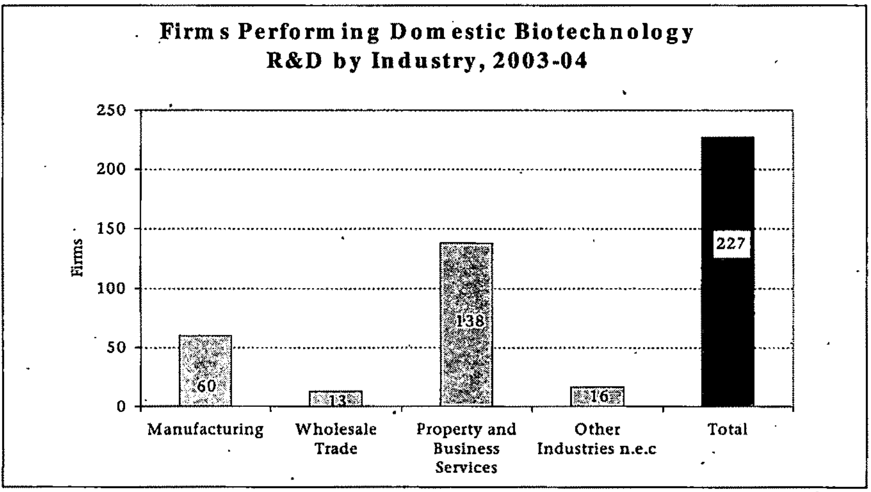
Biotechnology in Australia*

In recent part Australia has initiated some substantive measures to advance biotechnology. In 2003-04, 304 firms were directly or indirectly involved in biotechnology R&D. 227 firms performed



Distribution of 227 firms performing domestic R&D by application field, 2003-04



Firms Performing Domestic Biotechnology R&D by Industry, 2003-04

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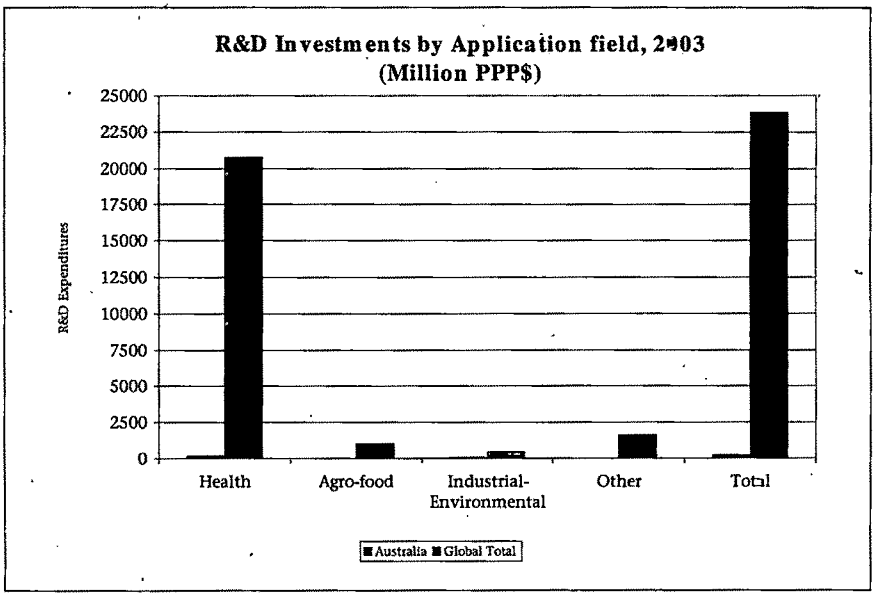
* Based on OECD (2006).

domestic biotechnology R&D while 78 of these firms also paid another organisation to conduct biotechnology R&D on their behalf. Another 77 firms only contracted out biotechnology R&D to another organisation (firm, university, etc.).

R&D Investments by Application field, 2003 (Million PPP $)

	Health	Agro Food	Industrial-Environmental	Other	Total
Australia	138.5	23.1	30.4	8.5	200.5
Global Total	20740.1	1027.1	456.3	1626.3	23849.7



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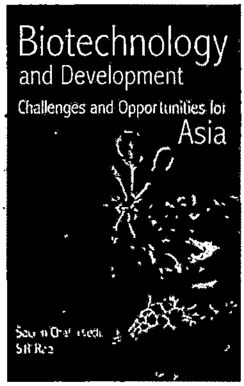

BIOTECHNOLOGY along with the other core technology viz. Information technology, is at the heart of technology revolution in Asia. Asian countries have adopted statrategies for harnessing the potential of biotechnology for their industrial development. The areas of applications both in pharmaceutical and agriculture sector have widened, finding new vistas of economic growth.

Policy challenges, however, are arising among other, concerning trade in GMOs, impact of genetic engineering on environment and human health, biosafety management, and ethical aspects that are yet to be addressed at any collective forum in Asia. One of the missing links is a dialogue between natural and social scientists so as to identify socio-economic requirements and policy priorities in the realm of biotechnology and development in the region.

Biotechnology and Development: Challenges and Opportunities for Asia
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Transnational Factors and National Linkages: Indian Experience in Human Vaccines

Y. Madhavi*

Abstract: This paper explores how transnational factors through international agendas/global policies determine and shape the indigenous technology development initiatives in the developing countries, using the case of vaccine development in India as an example. The institutionalization of vaccine research in India over a century and its trajectory of development reveal that the transnational factors shaped its research. In the post-independence period and during the post-biotechnology period, the policies of international agencies and the interests of transnational corporations directly or indirectly shaped the research and production pattern of vaccines to some extent. This study also reveals that in spite of the early institutionalization of vaccine R&D in India, inherent weaknesses in the national innovation system such as inadequate resources, weak in-house R&D, import dependency and inability to keep pace with modern technological developments made the Indian vaccine agenda vulnerable to international pulls and pressures.

Keywords: India, vaccine, policy, transnational; innovation system.

Introduction

Science and technology occupy an important place in the national policies of development in the modern world, especially in terms of contributing to improvement in the quality of human life. However, the mere existence of a strong science base does not necessarily guarantee technological competitiveness, nor does a success in technology development automatically guarantee production. This is much more likely to be true in a developing country context. Even in the West, simplistic assumptions regarding a unilinear relationship between science, technology and economic development forwarded by the pipe line theory have been replaced by more complex, multilayered, non-

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linear relationships as in the case of the chain linked model.[1] Moreover, the trajectory of technological development tends to be path dependent,[2] in the sense that the form and direction of technological changes in a developing country tend to be strongly influenced by the path established by the developed West. In such a situation, the development of indigenous capabilities gets complicated by the difficult choice between catching up with the developed countries on the one hand and concentrating on new frontiers on the other, and demands a certain degree of 'flexibility' and 'coherence' in the national innovation system.[3] The theory of capability requirements[4] provides a useful framework to model the entry of developing countries to catch up in any technology system. While several studies point out various key factors such as size of the firm and market characteristics,[5] institutional linkages,[6] interactive systems,[7] organizational environment,[8] etc., that shape the technological development, the present study focuses on how transnational factors and the institutions through which they are propagated shape the nationalist endeavours in the developing countries. Technological developments as well as socio-economic and political factors, across the countries that may influence the global and national endeavours have been referred to as transnational factors in this paper. While the above studies provide important leads that are contextual and geographical, this paper limits its focus to external influences on local capability building without denying the importance of other determinants of innovation. The technological development determinants cited above were studied mostly in developed countries, that too in the core sectors.

This paper focuses on one of the social sectors (i.e. preventive medicine development in primary health care), and analyses the role of external factors in shaping the indigenous technological capability for improvement of the health of the population through vaccination.

Methodology

The study is based on personal interviews with the heads, scientific staff of R&D institutions and companies' executives by means of the structured interview schedule. This information is substantiated with published literature such as research papers and the annual reports of vaccine R&D institutions, vaccine companies and the Department of Biotechnology. This paper analyses the human vaccine development in three periods. The focus of the study is on primary vaccines (TT, DT, DPT, BCG, OPV & Measles) that are included in the national immunization programmme. The attention on these vaccines would be discussed with a greater emphasis on the post-indepenidence period as the focus on it coincides with the declaration of the WHO 'Health for All' in 1978 and the reorganization of institutional production priorities accordingly. However, the development of traditional vaccines such as cholera, smallpox, anti-rabies, typhoid, Diphtheria toxoid, tetanus toxoid and Triple antigen (DPT) were produced as per the demand during the pre-independence period. The three watershed periods are:

1. Pre-independence period (pre 1947),
2. Post-independence period (post 1947),
3. Post-biotechnology period (post 1980).

Pre-independence refers to the period before India became independent in the year 1947. Post-independence period is the time span after 1947. Though the Post-biotechnology period forms a part of the post-independence period, special reference to this period is made because that would enable us to compare the spectacular S&T developments in the field of vaccine internationally and nationally after the emergence of the new discipline of biotechnology in the 1980s. This paper defines the post-biotechnology period as the period beginning from the year 1980 onwards.

Early Developments and Institutionalization of Vaccine R&D and Production

Vaccines are widely regarded as extremely important in primary health care as preventive medicines against infectious diseases. While there are strong arguments contrary to this notion (for example, see Philips 1996), such challenges have not been posed in the Indian context. In any case, resolving this debate is beyond the scope of the present study, as its main purpose is to understand the external factors that shape the trajectories of development of self-reliance in vaccines. It is also important to mention that by no means does this study underestimate the importance of other preventive measures in public health, such as good sanitation, hygienic living conditions and safe drinking water.

Vaccines comprise only 2 per cent of the global pharmaceutical market representing a nearly US$ 8 billion global industry, which is projected to grow to $10 billion in 2010. However, they are considered indispensable because of global immunization programmes. In 2001, worldwide spending on R&D for "biologicals", of which vaccines are the largest segment, was $1.1 billion (about 4 per cent of total private pharmaceutical R&D), dominated by a few large transnational corporations such as, Aventis Pasteur, Biocine Sclavo, GlaxoSmithKline Beecham, Chiron Behringer, Merck, Wyeth-Ledrle, etc. Many of these firms form a part of the global WHO-UNICEF vaccination programme (www.immunize.org). India is an attractive target for these companies due to its huge market. According to HAI News (1999), the pharmaceutical market in India is expected to grow to around 10 billion US dollars by 2010, maintaining a compound annual growth rate of 15 per cent with the increasing buying power of Indian consumers, especially the 200 million middle and upper middle class people, who are growing at a rate of 5-10 per cent per year. India's human vaccine market, estimated at over Rs.6800 million, is viewed as a gold mine by multinational and national manufacturing companies. Currently, the Indian vaccine market is estimated to be around $150 million. In 2002-2003, vaccines accounted for 57 per cent of the total Indian biopharmaceutical market with an estimated growth rate of 27 per cent in 2004. Tables 1 and 2 reflect that the number of private manufacturers have increased with new entrants in India in the post 1990s, in contrast to the shrinking number of global vaccine manufacturers. However, private manufacturers worldwide have shifted to the production of more new vaccines, leading to a demand-supply gap in primary vaccines. These recent trends that have major implications for the future of vaccine technology development, production, procurement and immunization strategies/policies in India are issues that are discussed in the current paper.

The Indian vaccine system offers an interesting and convenient example to study indigenous capability development for several reasons. The Indian government has identified vaccines as essential drugs, and is committed to expand the coverage of vaccination as a part of the global initiative towards achieving universal immunization. Moreover, it has adopted self-reliance in vaccine technology and self-sufficiency in vaccine production as a policy objective, and has taken the lead in encouraging indigenous technology development and production.

Table 1: Vaccine Manufacturers in India

Number of Vaccine Producers	Pre 1947		Post 1947		Post 1980		Latest (1995-2005)	
	Public sector	Private sector	Public sector	Private sector	Public sector	Private sector	Public sector	Private sector
All vaccines	15	5	18	10	23	8	**19	23
Primary Vaccine	#2+8	3	3	3	7	4	7*	10

Source: *Compiled* from Bhore Committee Report, Haiti Committee Report and Health Information of India, DGHS, MHFW, GOI, New Delhi.# Haffkine Institute & CRI Kasauli were the producers of DT, TT, DPT. However, there were 8 other companies that produced vaccines against plague, vaccine lymph, cholera and typhoid , as these diseases were rampant at that time.** 4 companies were closed down in post 1995. *3 companies were closed down by 2003-04.

Table 2: Number of Vaccine manufacturers in the world as on 1991

Country		Public sector		Private Sector	
		Primary Vaccines	New Vaccines	Primary Vaccines	New Vaccines
1.	USA	2	2	6	10
2.	UK	-	-	4	1
3.	Japan	-	-	2	2
4.	Korea	1	-	-	-
5.	Indonesia	2	1	-	-
6.	Czechoslovakia	1	-	-	-
7.	Yugoslavia	1	-	-	-
8.	Romania	1	-	-	-
9.	Russia	1	-	-	-
10.	Croatia	1	1	-	-
11.	Slovakia	1			
12.	Finland	1	1	1	-
13.	Italy	-	-	2	2
14.	France	-	-	1 (AVP monopoly)	1
15.	Switzerland	1	1	-	-
16.	Norway	1	-	-	-
17.	Denmark	2	-	-	-
18.	Germany	1	-	4	2
19.	Europe	1	-	2	1
20.	Spain	1	-	-	-
21.	Sweden				
22.	Belgium	-	-	1	2
23.	Australia	1			1
24.	Argentina	-	-	1 (AVP)	-
25.	Mexico	-	-	1	-
26.	Cuba	-	1	1	-
27.	Canada	1 (AVP monopoly)	1	-	-
28.	Brazil	2	-	-	-
29.	India	3	1		
30.	Egypt	1			

Source: Compiled from www.immunize.org

Pre-independence Period

The case study of vaccines is a unique and a very interesting example because vaccine research and development (R&D) and production in India are almost as old as the history of vaccine itself. Institutions for vaccine R&D and production evolved in India during the same period in history in which vaccination had gained importance and institutions were established for vaccine research in various parts of globe.[9] In fact, the organization of modern medical research in India started with vaccine research during British India, primarily to protect the imperial army against infectious diseases, coupled with the enthusiasm shown by the British medical researchers in India. The prevailing infectious diseases of India were specific to tropical climate and were not understood by the researchers in the native country of the colonial government leading it to set up different institutions. Some of the important discoveries made in India during this period were the discovery of aetiological agents of plague by Haffkine and by Paul-Louis Simond (demonstrated transmission of plague by fleas in 1898) and the identification of the vector of kala-azar by Short and Swaminathan. Waldemar Haffkine developed a plague vaccine in India for the first time in the world. Works of Ross on malaria and others on insect-based transmission of disease and their lifecycles were also done during this period. These discoveries had led to the opening up of a promising field of microbiology for medical researchers in India. The first bacteriological institute in India was founded in 1892 in Agra, followed by the establishment of the King Institute of Preventive Medicine (KIPM) Chennai (then Madras) in 1898, Haffkine Institute (HI), Mumbai (then Bombay) in 1898; Central Research Institute, Kasauli (1905); and Pasteur Institute of India (PII), Coonoor (1907). Until these institutions came up, no regular organization existed to carry out medical research in India. By 1930, there were around 15 such institutions in India, which developed, produced and supplied vaccines and sera to defence organizations in the country.[10]

There were also a few private companies such as Bengal Chemicals and Pharmaceuticals Ltd. (BCPL), Bengal Immunity Ltd. (BI) and Smith Strainstreet & Co. Ltd., in Kolkatta (then) Calcutta that produced biologicals (vaccines & sera). Several firms that were set up during the war produced biologicals under much more satisfactory conditions than was formerly the case.[11] Though both state supported institutions and private companies served during critical times such as epidemics and during World Wars I and II, research was mainly carried out in public-sponsored institutions. These institutions developed indigenous vaccines & sera against rabies, tetanus, diphtheria, pertussis, cholera, smallpox, typhoid and anti-snake venom, which were rampant at that time.

The techniques of production were much simpler; either heat inactivated or attenuated crude preparations of disease-causing organisms. The technology was not very well developed to produce entirely pure preparations and, therefore, could not ensure the safety and standardization of the dose all the time. Yet, these crude vaccines/sera were able to reduce the mortality to a large extent in the army and the native population during epidemics, though there were occasional controversies/conflicts due to the post-vaccination deaths. However, in the years that followed, increased demand for production/supply of vaccines & sera during the epidemics and World Wars I and II, have transformed these research institutions to mere production units, thus minimizing the research agenda to a limited activity of these institutes as several persons were transferred to do services for the army. After the war, the situation in many of these institutions was pathetic. These were run with a bare minimum of infrastructure, manpower, and resources. Coupled with after war effects, the socio-political and economic situation in British India was unstable with India's independence movement. Moreover, the colonial state's short sighted imperial interests of those times could not lay the foundation for a sustainable path for the technology development of vaccines and only short-term research and production needs were encouraged.[12] By the time India became independent these institutions actually reached some kind of a transition phase with the aftermath effects of war, where they required drive, direction and focus for restructuring of the organization and resources.

Post-independence Period

After independence, while the old institutions continue to exist without any radical transformation to foster R&D, at a time when the inter-disciplinary system began to gain importance in innovations elsewhere in the world, new institutions such as National Institute of Virology, Pune (the Poona) (in 1952 by partial support from the Rockefeller Foundation), Tuberculosis Research Centre, Madras (in 1956 under the joint auspices of Indian Council of Medical Research (ICMR), WHO, and British Medical Research Council), National Institute of Cholera and Enteric diseases, Calcutta (1962), Institute of Cytology and Preventive Oncology (1979), Rajendra Memorial Research Institute of Medical Sciences at Patna in 1981(to do research on kala-azar and other parasitic diseases), Enterovirus Research Centre (1981), Regional Medical Research Centre, Dibrugarh (1982, to study malaria, Japanese Encephalitis were set up in India by the Indian Council of Medical Research (ICMR)[13] and National Institute of Immunology (set up by DBT with partial support from the Population Council USA) dedicated to only R&D during the period 1950-1980.

India was at par with the world in vaccine technology development till the 1930s. After the 1940s, the technology development gap between the world and India increased so much so that even the introduction of improved techniques for known bacterial vaccines (Tetanus toxoid (TT), Diphtheria toxoid (DT), Diphtheria, pertussis and tetanus toxoid (DPT)) happened in India almost a decade after their introduction elsewhere in the world. By the time biotechnology revolution began, India was left far behind when compared to the technology development in the West (Madhavi 2005).

The first Committee on the Health Survey of India, pointed out in its report as far back as in 1946, that the mortality due to infectious diseases was very high in children, and that India needs to improve child health if it has to improve the health of the nation.[14] However, no clear strategies were adopted by independent India except in spurts as and when the demand was felt. For instance, A Bacillus Calmette-Guirin (BCG) vaccine Laboratory was set up in 1951 at Chennai (then Madras) with the help of United Nations Children's Fund (UNICEF) and its regular use was recommended. Accordingly, house-to-house BCG vaccination was carried out for some years. However, regular immunization of all children by BCG vaccine was articulated only in 1978, in alignment with the WHO's policy of 'Health for All' by AD 2000 (Annexure 2). In another instance, the Pasteur Institute of India (PII), Coonoor, which used to produce only the anti-rabies vaccine for South India, set up an Oral Polio Vaccine (OPV) production unit as a project in 1967 with support from WHO and the Government of India, based on the advice of Dr A. B. Sabin (who developed the oral polio vaccine) during his visit to India. The seed virus was obtained from the Institute of Poliomyelitis and Viral Encephalitis (IPVE), Moscow. The first batches of OPV were tested at the Medical Research Council laboratories, UK, through the good offices of WHO before it was used for immunization (Pasteur Institute Souvenir, 1907-1967). Since then, PII supplied OPV to the entire country till 1976, when one of the OPV batches was found to be reactogenic when tested at the Central Research Institute, Kasauli and the Haffkine Institute, Mumbai (then Bombay).

The government ordered PII to stop OPV production and prepare instead, for the production of bacterial vaccines (DT, TT, DPT) on a regular basis. Accordingly, the S&T personnel were trained at the Central Research Institute, Kasauli, and the production of bacterial vaccines started in 1978 (information based on personal interviews with PII staff at Coonoor). Strangely, there is no evidence of any attempt to rectify the problem in OPV either at PII or elsewhere. Equally strange is the fact that despite a few subsequent attempts, India could never master the technology to produce OPV indigenously in the public sector, as discussed in the later sections.

India launched an Expanded Programme on Immunization (EPI) in 1978, to meet the objectives of the "Alma Ata" Declaration of WHO in 1978. Accordingly, several state-supported old vaccine R&D institutions such as CRI Kasauli, HI Mumbai, PII Coonoor, Institute of Preventve Medicine, Hyderabad, etc., were restructured for the production of the DTP group of vaccines. With the declaration that India was smallpox free in 1976, institutions (for example, KIPM, Chennai, Vaccine Institute Belgaum, Pasteur Institute Shillong, etc.) that were producing the smallpox vaccine stopped production and started the manufacture of TT, DT and DTP. One more significant development that took place during this period was that the Indian government took over private companies such as BCPL (1980), BIL (1977), SSPL (1977), West Bengal Lab (1980) Calcutta, Vaccine Institute Baroda (1973), and Vaccine Institute Nagpur (1980). Thus, the public sector units that produced primary vaccines increased in number during this period (see Table 1).

The common factor that shaped vaccine technology development both in the old and new institutional structures (to some extent) has been the international health policy regime, besides the intrinsic problems associated with the institutional structures in post-independent India. India became a member country of the World Health Organization (WHO) soon after this was established in 1948 to control disease transmission across countries. WHO set up regional centres in its Member countries to monitor disease prevalence and co-ordinate their control. The regional centres in India were located in the existing (old) vaccine institutions which were already over-burdened with routine production and supply functions. Since monetary support was available, epidemiological investigation became a research priority in these institutions, thus marginalizing other research activities for the development of new or improved vaccines. Similarly, vaccine R&D institutions that were set up in the post-independence period also largely conducted disease monitoring, post-immunization studies and clinical trials, as financial support was available to such investigations. Though some of these new institutions did develop vaccines (Japanese Encephalitis by National Institute of Virology, Pune and leprosy vaccine by National Institute of Immunology, New Delhi) very few have reached the market.

Vaccine Scenario in Post-Biotechnology Period in India

Scientific and technological developments in the life sciences were rapidly increasing in 1970s with the emergence of greater specialization and new disciplines such as molecular biology, immunology, biotechnology, etc. These advances contributed to new techniques of production and superior products for improving the quality of life and also impacted the economy. Using these new bio-techniques, several existing vaccines were improved in the West and new vaccines were developed that were safe and potent when compared to conventional vaccines. Biotechnology was also being increasingly viewed as a tool to enhance production and benefit the economy in the process. Several countries adopted policies to foster biotechnology and harness the fruits of biotechnology in their economies. In response to the S&T developments in the West, the Government of India set up the National Biotechnology Board in 1982, which was subsequently established as a separate Department of Biotechnology (DBT) under the Union Ministry of Science and Technology in 1986. The Government of India further intensified immunization efforts against vaccine-preventable diseases by launching the Universal Immunization Programme (UIP) in 1985 and a National Technology Mission on immunization in 1986. This was jointly implemented by the Ministry of Health and Family Welfare (MHFW) and DBT, with the former acting as a nodal agency. DBT was entrusted to fill the R&D gaps in vaccines to enable the country to achieve self-reliance.[15] UIP observed the existence of a gap between the supply and demand of vaccines, and that India was entirely import dependent for its measles and polio vaccine requirements due to the absence of a strong R&D base (DBT Annual Report 1987-88). DBT promoted research on vaccines by (1) sponsoring R&D projects to develop vaccines in various institutions in India such as the National Institute of Immunology Delhi; Indian Institute of Science, Bangalore; All India Institute of Medical Sciences, Delhi; Central Drug Research Institute, Lucknow; National Institute of Virology, Pune, etc.[16] (2) DBT also signed a Memorandum of Understanding on an Indo-US Vaccine Action Programme (Indo-US VAP) to foster R&D in vaccines (Refer to Box 1). (3) DBT also attempted to foster the indigenous production of vaccines by setting up two public sector units for the indigenous production of OPV and the Measles vaccine. However, these objectives could not be achieved in the later years owing to the pressures of globalization and liberalization post 1990s. The following section discusses how transnational factors directly or indirectly influenced the indigenous vaccine development and production in India.

Box 1: Indo-US Vaccine Action Programme (VAP)

In 1987, the Government of India signed a memorandum of understanding (MOU) with United States of America (USA) to initiate a joint Indo-US Vaccine Action Programme (Indo-US VAP) to develop vaccines. This was a high profile agreement that involved the then Indian Prime Minister Rajiv Gandhi and the then US President Ronald Reagan, and was initiated during an earlier visit of the then US Secretary for health and human services, Dr. Otis R. Bowen. The objective of the MOU was 'to bring together Indian and US scientists to jointly develop and test new and improved vaccines for immunization against diseases and to focus upon vaccine production, quality control and delivery methodology', and US promised assistance of around $ 6 million through USAID for this purpose.

The following were the issues raised by the opponents of VAP.

- It has bypassed all the regular channels of decision-making including ICMR and high power biotechnology scientific committee to scrutinize the project if it concerns any biological warfare implications in the interest of national security and public health.[17] These concerns were based on the earlier experience of India with US scientists in 1974, when it was found that the information was leased out to an American leading defence organisation.[18]
- It was an unequal agreement, where US exercised much more control and India cannot review nor implement research programmes without US approval (Bidwai 1987, see notes in reference for details).

Box 1 continued

Box 1 continued

- Biotechnology firms in the West were under severe economic pressure to put their products on the market, and most of the US vaccines were under advanced stage of development waiting for clinical evaluation, Indian scientific community feared that India may become an experimental ground as stringent rules were either not in force or could not be enforced effectively.
- The clinical trials conducted under the Indo-US VAP would produce new vaccines by the US companies and will be sold back to India at exorbitant prices.[19]
- As a part of Indo-US VAP, USA allocated $1.62 million to establish an epidemiology research and training centre in Madras (now Chennai). This would make the most vital information regarding the Indian population would be made available to US which could be used in biological warfare.
- At that time it was agreed upon that within 90 days of signing of MoU, patent provisions will be developed and agreed upon to suit mutual interests. Fears were expressed that this may mean the replacing the Indian Patent Act of 1970 with strong US style system of patent protection, which is prevalent in the industrialised developed countries.[20]
- The Indo-US VAP agreement may come in the way of setting up Indian R&D centres in Vaccines (*Times of India*, 30 August 1987) to tackle local priorities.

External Factors and the Shaping of Technology Choices and Policy Options

The Indian government introduced six vaccines against childhood infectious diseases, i.e. tetanus, diphtheria, pertussis, tuberculosis, polio, and typhoid for regular immunization of children under the Expanded Programme of Immunization (EPI) in 1978, only after the global agenda for childhood vaccination was articulated by the WHO. Among these, the technologies for TT, DT, DPT, and BCG were known which were simpler and the existing vaccine production organizations could produce them in the country. In 1985, a vaccination against Measles was introduced under EPI. Even though the technologies for inactivated polio vaccine (IPV), oral polio vaccine (OPV) and Measles were introduced in the world in 1955, 1962 and 1963, respectively,[21] they were not available in India for indigenous production. Since the launching of EPI in 1978, India was dependent entirely on imports for OPV and measles vaccine for two decades. This raises some pertinent questions: Why could India not achieve technological self-reliance in these two vaccines, despite an early start and fairly good institutionalization of vaccine research in the country? Why was technology choice between IPV vs. OPV not assessed and an appropriate course not adopted based on an assessment of the pros and cons? Though the Pasteur Institute of India, Coonoor, produced OPV indigenously for the entire country successfully for a decade (1967-1976), it was stopped due to reactogenicity. Why was the limitation never rectified? Instead, import of OPV was resorted to? Despite DBT's attempts, why could OPV never be produced in the Indian public sector thereafter?

The World Health Organization recommended the use of OPV in countries where polio was highly epidemic and endemic. Because of its easy administration, its ability to afford herd immunity (which occurs when the immunization of a population results in a decreased incidence of disease in the unimmunized remainder of that population) and low costs (one-tenth of IPV), this vaccine was recommended for mass immunization. However, since it was temperature sensitive, cold chain was a crucial factor in the success of OPV immunization, especially in the rural areas of tropical countries like India. The Indian government adopted it primarily because the WHO recommended it, and because it could be procured at a cheaper price through the United Nations (UN) procuring system. It is tempting to ask why WHO, which provided the technical know-how for indigenous production of the small pox vaccine in India at KIPM since 1965 (KIPM 1985), did not show a similar zeal in the case of OPV. Similarly, was the Indian Government's decision to launch the production of bacterial vaccines (after stopping OPV) at PII-Coonoor entirely based on indigenous considerations? Was it meant to fall in line with WHO's launch of the 'Health For All' programme in 1978, even prior to the launching of EPI in 1978 in India? IVCOL planned to produce vero cell culture based OPV instead of IPV as per the recommendations of WHO and MHFW (DBT Annual Report 1991-92). However, even this plan was also shelved as the company was closed in 1997. Why was OPV production not attempted again in any other national lab or vaccine institute for a long time? Was it due to any external influences? Were they prompted by the vested interest of transnational companies that may have lobbied with the decision-makers in WHO or in the Indian Government to discourage indigenous production and ensure a captive market for their products? Alternatively, was the Indian Government genuinely concerned about the expected public fear/public acceptance of vaccination? If it was really concerned, why didn't it improve the standards of quality control such as good lab practices (GLP) and good manufacturing practices (GMP)? These questions have been addressed in the later sections, but the immediate issues relating to the choice between OPV and IPV are dealt with below.

There have been several newspaper reports about polio cases after OPV immunization using imported vaccines.[22] This could mean that either the imported vaccine was ineffective for some reasons, or maintenance of the cold chain was still a limiting factor in achieving the eradication of polio in India. However, even in the USA, where polio has been almost eradicated using OPV, cases of polio have been reported after vaccination, prompting the Action Committee on Immunisation Practice (ACIP) to shift towards the use of IPV in its national immunization programme in a phased manner-using a combination of IPV-OPV schedule initially, followed by a complete shift to IPV recently.[23] Similarly, European countries such as Sweden and Holland could successfully eliminate polio using only IPV. Some western countries as well as some African and Asian countries adopted a combination of IPV-OPV usage.[24] Apart from safety reasons, for a tropical country like India with erratic (if not total lack of) rural power supply and inadequate refrigeration facilities, use of IPV that was more stable at room temperature would have been a better choice. Alternatively, a cost benefit analysis of the available options would have given a better feedback for the choice of the right product/technology that suited Indian conditions. However, there is no evidence of any such official exercise being done. Unfortunately, unlike in western countries, which have a strong consumer awareness and strict enforcement of consumer/public interest laws and compensation policies[25], Indian officials acknowledged no such public concerns and did not face strong public pressure or litigation.

There is also no evidence for any objective basis for India's adherence to OPV as against IPV and its continued imports, other than that of falling in line with the WHO policies. Some argue that even though IPV in India was always effective OPV was recommended in developing countries because international organizations were trying to find new markets for the US multinational corporations, since the market demand for OPV ceased to exist in the US and other developed countries by the end of twentieth century.[26] However, it is interesting to note that the Indian medical community is recently debating over the use of OPV in EPI and some recommend the use of IPV instead of OPV. The debate on this issue was spurred on after the United States decided to use IPV instead of OPV in their immunization programme (UN wire, 29 June 2000). Critics point out that the local field realities such as evaluation of actual protection levels achieved after the pulse polio immunization (OPV), recording of the actual number of vaccine-associated polio paralysis cases (VAPP), and an assessment of wild polio virus in the population, etc. were not taken into account while considering the policy of polio eradication in India. They point out that the nature of the polio virus transmission is such that it cannot be eradicated, but can only be controlled as the virus transmits silently over many years even if there are no paralytic polio cases. They emphasize that OPV is not effective in immunocompromised children and they recommend the use of IPV to tackle the cases of VAPP and the wild poliovirus transmission in the local population.[27]

The Case of OPV and Measles

An independent cost-benefit study in India revealed that indigenous production of OPV was more economical than importing it.[28] However, such studies did not receive due attention in the decision-making mechanism, and more often than not, the policy decisions seem to be guided by other considerations. After the formation of DBT in 1986, it took up an ambitious objective to make India self-reliant and self-sufficient in vaccines using new technologies of production for OPV, IPV, measles, DPT (with improved pertussis) and tissue culture-based anti-rabies vaccine, in addition to DT, TT and Hepatitis B. As a part of this effort, DBT set up two public sector units, the Indian Vaccine Corporation Ltd. (IVCOL) at Gurgaon and Bharat Immunological and Biologicals Corporation Ltd., (BIBCOL) at Bulandshar in 1987. The objective was to meet the growing demand for vaccines in the Indian market by repackaging these from imported bulk initially, and to absorb/develop the technology for indigenous production subsequently. However, the target date for the initiation of indigenous production was postponed each year, and repackaging and supply from the imported bulk continued for OPV at BIBCOL and for the measles vaccine at IVCOL, till both the units were eventually declared sick. IVCOL was closed down for non-availability of the measles technology.[29] DBT had planned to transfer this technology from a French public sector company, which itself was privatized in the meantime, and the new owners refused to transfer the technology to the Indian joint venture.[30] Perhaps, selling technology was no longer an attractive option when direct access to the Indian market was becoming available to foreign companies under the Indian economy policies of liberalization and globalization, which were imposed on the country since 1991 as prescribed by the International Monetary Fund and World Bank. It is tempting to ask why the option of repackaging either from France or elsewhere, from imported bulk was not attempted at IVCOL, nor any efforts continued to find alternative means for indigenous manufacture.

The production of OPV in BIBCOL formed a part of the bilateral agreement between India and Russia for long-term integrated S&T co-operation, which was signed in 1987. As Russian industry did not have the resources to target global markets with its domestic technologies due to its sluggish economic condition at that time, Indian officials should have anticipated easier access to vaccine technology for the Indian industry. The project of OPV production in BIBCOL has no technology transfer from other countries. However, the Institute of Poliomyelitis and Viral Encephalitis (IPVE) at Moscow agreed to 'Technology Consultancy Co-operation' for OPV production at BIBCOL on the condition that India should import OPV in bulk from Russia in the first phase in its memorandum of understanding (MOU). According to the MOU, IPVE, Russia would provide the knowledge on basic know-how, supply of seed virus, training of S&T personnel, quality control of the first six batches and certification of first six batches according to WHO standards. The technology for indigenous production was to be utilized in the second phase, by which time the production facilities were established at BIBCOL. However, the first phase, which started in 1992 continued year after year, postponing the entry into the second phase for indigenous manufacture of OPV. Interestingly, BIBCOL's source for technology and bulk import was the same Russian institute (IPVE) from which PII obtained its technology two decades ago, but had stopped production after a decade due to objections over reactogenecity. This raises some important questions. Was BIBCOL obtaining a better vaccine (or technology) than the OPV produced by PII earlier when using technology from the same Russian source? If not, was it free from the reactogenecity reported earlier, or was the earlier objection over reactogenecity not genuine? If the objection was genuine, was it really a problem of production at PII, or was it inherent in the technology sourced from IPVE?

In the meantime, BIBCOL's main customer, UNICEF, seems to have refused to purchase its repackaged vaccines of Russian origin. India's polio vaccination programme is supported by UNICEF, which procures the vaccines from the companies on behalf of its donor (predominantly Western) nations and makes them available for end users in India. As per the new procurement criteria introduced in 1998 (WHO/VSQ/98.05), all the vaccine suppliers to UNICEF had to have a mandatory GMP certification from WHO, which IPVE, the Russian partner of BIBCOL, did not have and perhaps had never even applied for one. This meant that BIBCOL would not be able to supply the OPV imported from Russia to UNICEF as long as BIBCOL and IPVE did not have a GMP certification. It would be difficult for BIBCOL to find other customers, as long as the Indian polio vaccination programme depended on UNICEF's support (and therefore its procurement criteria). Naturally, India's commitment to buy OPV in bulk from Russia was suspended in 1998 on the grounds that the supplier (IPVE) did not have the WHO accreditation based on GMP certification (Somasekhar 1998). During that year, BIBCOL sourced its OPV bulk from SmithKline Beecham (SKB), Belgium, and Biopharma, USA. Western drug multinationals such as SKB, Biopharma, Chrion and Pasteur Mereiux, France, are among the major WHO-approved, GMP-certified suppliers for UNICEF.

Curiously, it appears that soon after BIBCOL changed its import partners, its manufacturing infrastructure was certified as GMP compliant, following a visit by the WHO team in 1998-99. Within months, BIBCOL also obtained the approval of UNICEF as a supplier. From the bulk imported from its new partners, BIBCOL supplied 70 million doses of OPV to UNICEF and the company had a turnover of Rs. 552 crores with a net profit of Rs. 70-80 lakhs during 1999-2000.[31]

The above developments raise certain very pertinent questions: Was UNICEF unaware of its own procurement standards till 1998 or were they made more stringent to suit some firms or keep out some others? In other words, was GMP certification a ploy of Western MNCs to end the Indo-Russian collaboration to access the Indian market? In that case, would India have got a GMP certification if it were to indigenize the OPV production before 1998? Going further, would it have made a difference (to obtain GMP certification) whether the indigenization of OPV production was based on Russian technology or locally developed technology or even perhaps some Western technology?

It is also pertinent to ask why the indigenous production of OPV was never started in BIBCOL? Though the S&T personnel of BIBCOL were trained at IPVE, Moscow, it was not very clear whether the seed virus was supplied to start the indigenous production in phase II according to MOU. Was it because of uncertainty over the GMP certification? In that case, was BIBCOL aware of the GMP requirement but was unsure of obtaining it if the manufacture was done indigenously? According to the managing director of BIBCOL, starting indigenous production of OPV at that juncture would have taken two and a half years, by which time indigenous production may no longer be commercially viable, as the projections were that polio may be eradicated in the next three years.[32] But then, it is not clear what prevented BIBCOL from indigenizing production much earlier to save on imports whether from Russia or elsewhere. With the continuing demand for OPV and no signs of total eradication of polio yet, the wisdom (if not motive) of BIBCOL's decision not to enter into the second phase in spite of having excellent infrastructure (pre 1998) and GMP certification (post-1999) becomes questionable.

In the meantime, competition from the entry of domestic private companies like Panacea Biotech pushed back BIBCOL even further. Eventually, BIBCOL was declared a sick unit in 2000 and handed over to the Board of Industrial and Financial Reconstruction (BIFR) for revival.[33] BIFR, based on a diversification plan submitted by the Industrial Development Bank of India (IDBI), recommended the production of BCG, measles and tetanus toxoid vaccines to generate additional revenue, which was approved recently. Interestingly, BIBCOL will continue to tie up with IPVE, Moscow for production of the BCG and measles vaccine. The company has also been exploring the options of producing the Hepatitis B vaccine on a joint venture basis, with domestic companies such as Shanta Biotech, Cadila, etc. It is intriguing to note that a company which has virtually all 'immunologicals and biologicals' mentioned in its name had to go through BIFR for 'diversifying' its production from one vaccine (which was never produced) to the other. In the end, a public-sector company meant to bring about self-reliance in the production of primary vaccines, if revived at all, continues to depend on imports and foreign collaborations. The only vaccine that it may be able to produce using indigenous technology is Hepatitis B (though not developed in BIBCOL), which is not among the primary vaccines for which the company was originally established.

The failure of indigenous OPV production and the fall of BIBCOL is an example of how external factors such as international relations, the policies of WHO/UNICEF, and possibly of their donor nations or their companies, can define the fate of a perfectly legitimate policy objective of achieving self-sufficiency in vaccine production and self-reliance in vaccine technology. Walt (1994) observed that even though developing countries have a good voting strength in UN organizations such as WHO, this is a much weaker tool than the industrialized countries' potential of withdrawing their budgetary contributions, and moreover for practical reasons they are generally unwilling to oppose the donors who provide their countries with technical and financial assistance.

Private Sector's Role in Primary vaccines

Traditionally, the private sector's participation was negligible in primary vaccine R&D and production worldwide and in India. The vaccine market accounted for a meagre 0.3 per cent (USA) and 0.1 per cent (India) of the total pharmaceutical market (Anonymus 1985) (Indian drug statistics, 1985-87) even till the mid 1980s. Of the total human vaccine market in 1985, the private sector in the US accounted for sales of around US$ 170 million.[34] The number of private vaccine manufacturers that produced primary vaccines also came down in India (see Table 1) and other countries alike in the 1980s For instance, there were around 10 manufacturers in the mid-1970s and by mid-1980s there were only 3 companies (Connaught Laboratories, Wyeth Laboratories and Lederle Laboratories) in the US that produced primary vaccines, due to the impact of the stringent regulatory system on vaccine liability issues coupled with a static product range and low profit margins in primary vaccines. However, this trend has changed the world over, especially during the post-biotechnology period in the 1990s where a few large private vaccine manufacturers have come to dominate a large share of the vaccine market with large investments in the development and production of new vaccines.

Similarly, in India too private sector participation increased in the post-biotechnology period, especially after the introduction of liberalization in India under the changed global trade regime. Though new technological developments coupled with the stringent Intellectual Property Rights regime provided the right background for entry of the private sector, the decline of the public sector and the liberalization policy have facilitated its easy entry to supply vaccines to EPI in India. For instance, Serum Institute of India, Pune, a private company, bought technology from London and has been supplying the entire measles requirement for the country since 1992.[35] Radicura Pharma, another private company in India, has been supplying OPV to EPI for a long time. However, this transition from the public sector era to the privatization and liberalization era was not smooth, and often led to tensions between the two sectors. For instance, in 1997, Haffkine Biopharmaceutical Ltd. (HBPCL), a public sector company started its indigenous production of OPV with the seed virus obtained from elsewhere.[36] However, its regular supply to EPI was discouraged by the government alleging that the OPV supplied by this company was not potent, but the company claimed that the allegation was false and that the government was supporting the private companies, whereas Haffkine Biopharmaceutical Ltd. would incur loses if the government does not buy the product from them.[37] It is ironical to note that private companies of the pre-independence period (BCPL, SSPL, BI), which were made public during post-independence period (1977-80) to meet the objectives of EPI, were declared sick (1993-94) and closed down owing to the pressures of liberalization. Also a hundred year old public sector institutions like IPM Hyderabad, State Vaccine Institute, Patwada Nagar were closed down during 2003-04, and in some institutions (The Pasteur Inst., Shillong; Government Vaccine Institute, Namkarim, Ranchi; Vaccine Institute, Baroda; Vaccine Institute, Nagpur; West Bengal Vaccine Lab, Calcutta; Public Health Institute, Patna; and State Health Vaccine Institute, Lucknow) the production of traditional vaccines (cholera, anti-rabies, typhoid, TT) has been stopped since 1997-98, and it is likely that they might be closed down.

While the public sector focused on EPI vaccines, Indian private companies have largely focused on high value vaccines outside the EPI. For instance, Hoechst-Marion Roussell (India) and Cadila, Ahmadabad, India have been working on the development and import of an oral and injectable typhoid vaccine; Hoechst is producing an anti-rabies vaccine; and Cadila has a genetically engineered vaccine against Hepatitis B in the advanced stages of development. Glaxo, Biological Evans Ltd. and the Serum Institute of India account for a large share of the DTP vaccine production, but relatively few companies were working on Hepatitis B and OPV.[38] Thus, the attempts to achieve self-sufficiency in vaccine production and self-reliance in vaccine technology through the public sector got diluted over the years. Though private sector companies have filled the gap in some cases, the majority of them have been focusing their efforts on new vaccines and non-EPI vaccines. One of the main reasons for the growing gap between demand and supply of primary vaccines in India is that while the public sector production is on the decline, vaccine availability from the private sector or through the UNICEF procurement mechanism has not improved.[39] This trend is a worrisome global trend that has been acknowledged by UNICEF (http://www.unicef.org/supply/index_vaccine_security.htm). There is no guarantee that the private sector would provide primary vaccines at affordable prices, and especially when they are not worried by local competition or by the stringent price control regimes of the government. The last decade has witnessed a systematic dilution of the Drug Price Control Order by the removal of several drugs from price control.[40] Vaccines are so far still under price control, but going by the current trends, it may not be surprising if they are removed from price control in the future.

To add to the problems in primary vaccines used under the EPI, pressures have been building up to introduce some of the newly-developed vaccines into the EPI, such as those against Hepatitis B, Chickenpox, Rubella, Meningitis, Influenza type B, etc. being produced by private firms and transnational corporations. The case of Hepatitis B vaccine introduction in India is a good example. The big business in Hepatitis vaccines started with the introduction into the market of the plasma-derived and recombinant Hepatitis B vaccine by Merck & Co., and Smithkline Beecham Ltd., fetching them millions of dollars in profit. Three new private companies were set up around the mid-1990s to produce the Hepatitis B vaccine and several private companies too created demand for the Hepatitis B market in India by various means. At the same time, this has led to increasing the pressure for including the Hepatitis B vaccine under the EPI. This has already triggered public debates, with several public health activists and non-governmental health organizations arguing that the prevalence of Hepatitis B in the Indian population is not uniform and the disease burden is far less when compared to other infectious diseases, and therefore, the costs and benefits of introducing such high cost vaccines in the EPI need to be weighed more carefully.[41] On the other hand, the Joint Working Group on the Indo-US Vaccine Action Programme has recommended the use of Hepatitis B in the EPI. Similarly, vero cell culture based rabies vaccine from PMSV, France was introduced in the Indian market through a tripartite agreement between PMSV (France), Alidac Genetics & Pharmaceuticals (Ahmedabad) and IVCOL (New Delhi) in India (DBT *Annual Report, 1991-92*). The growth of the vaccine industry in the private sector, especially in the non-EPI vaccines (dipththeria, pertussis, tetanus toxoid conjugated with IPV, oral typhoid, tissue culture based measles and anti-rabies, influenza type A and type B, rotavirus vaccine, rubella, mumps, meningitis, etc.), has fuelled the demand to include new vaccines in the EPI. EPI provides a huge captive market in a populous country like India, and the decline of the public sector and increasing influence of private sector and TNCs on international health agencies brings Indian mass vaccination policies under tremendous pressure.

New global alliances and their impact on developing countries

The 1990s witnessed new global alliances, which are formed to promote the development of vaccines through global net works and through bilateral/multilateral programmes (see Table 3). The background for the formation of global networks was prepared by organizing several international conferences on health research, stressing the fact that almost 90 per cent of the global disease burden is in developing countries (Murray and Lopez 1996) and their total investment in R&D amounts to only 4.4 per cent.[42] These conferences were also mostly spearheaded and sponsored by UN organizations and TNCs, ostensibly on behalf of the developing countries. However, it was argued that the research

Table 3: Transnational (Global) Alliances

Alliance	Year of launching	Objective	Sponsors	Remarks	Reference
Children Vaccine Initiative (CVI)	1990	To develop global strategies for development & utilization of vaccines	UNICEF, WB, UNDP, WHO, RF, Worlds largest manufacturers and the marketers		Fisher (2000), co-founder of National vaccine information Centre, www.nextcity.com
Global Programme on Vaccination (GPV)	1990	New vaccine development programme to purchase and supply vaccines to EPI	Sponsors of WHO	A superior policy making unit within the WHO	Greenouh and Streefland, Social Science Research Council, (1998), 52(1),1-16.
International AIDS Vaccine Initiative (IAVI)	1996	To develop antivirals against HIV for the world. Encourages industry participation and supports vaccine development partnerships.	Governments of UK, Netherlands and Canada, WB, the Bill and Melinda Gates Foundation, RF, Sloan Foundation and Starr foundation	More than 35 vaccine candidates undergoing trials at present	www.iavi.org www.dnavaccine.com HIV update, PR Newswire, South Africa, 11th July, 2000
Medicines for Malaria Venture (MMV), an entrepreneurial non-profit international organisation		To create incentives to develop new drugs & vaccines. To improve private sector participation and to eradicate malaria burden by 2010. To supply vaccines at cheaper prices to poor countries	RF, WB, SKB, Wellcome Trust, UK depart. for international development, IFPMA, the association of British Pharmaceutical industries, Philanthropic donations & foundations.	Any vaccine discovery may be patented, but the owner of the patents would be MMV, and Pharmaceutical companies can market the vaccine products	www.malariamedicines.org

Table 3 continued

Table 3 continued

Alliance	Year of launching	Objective	Sponsors	Remarks	Reference
Global alliance for Vaccines and Immunization (GAVI)	1999	Every child in the world would be protected against vaccine preventable diseases	Bill and Melinda Gates Foundation, IFPMA, Public health and research institutions, national governmenst, RF, UNICEF, WB, WHO.	Co-ordinates Immunization programmes at regional, national and international levels. Accelerates R&D, development and introduction of new vaccines to achieve sustainable immunizations.	www.vaccinealliance.org
Malaria Vaccine Initiative (MVI)	1999	To accelerate and develop vaccine candidates against malaria. To ensure their accessibility to developing world.	Bill & Melinda Gates Foundation	MVI constituted with the scientists from NIH, NAID, Water Reed Army Institute, Hopkins University of Preventive Medicine and RAND corporation. MVI works with GAVI to explore commercialization, procurement and delivery of vaccines to primary health sector	www.malariavaccine.org

Source: Compiled from different sources.IFPMA: International Federation for Pharmaceutical Manufacturers Association, RF: Rockfeller Foundation, UK: United Kingdom, UNDP: United Nations Development Program, WB: World Bank, UNICEF: United Nations Children's Fund, SKB: SmithKline Beecham, WHO: World Health Organisation.

agendas are seldom developed with the active participation of developing country research leaders and communities.[43]

The structure of these global alliances reveal that the major players are transnational corporations, the UN system and the G7 countries (United States, Japan, Germany, France, Britain, Italy and Canada) that articulate the policies for the world (see Table 3). The rich industrialized countries also have significant influence on policies inside or outside UN agencies, as G7 countries are important funders of extra-budgetary programmes. Another major source for policy guidance on development and aid-related issues is the World Bank whose prescriptions for a market-driven approach over the past decade proved to be an embarrassment.[44] It is a well-known fact that the TNCs are involved in almost every global industry and 90 per cent of all technology and the product patents worldwide are held by them. Scholars have cited that TNCs are among the most effective engines of development and also as one of the most powerful impediments to the third world development.[45] This is particularly true in the case of vaccines, as described earlier in this paper and by others in literature. As Greenough and Streefland (1998) put it,

> 'vaccine technology represents a biomedical intervention with truly global ramifications. Strategic policy formulations, target setting and prioritization in funding have become transnational process with a wide range of actors orchestered by global actors such as Child Vaccine Initiative. Though the implementation of vaccination programme is a national programme, the transnational decision-making have become an integral part of public sector health service delivery'.

The demand for vaccine markets is articulated through various means. For instance, developing countries are lured by the free donations of vaccines and large amounts of monetary aid by industrialized countries and TNCs, thus generating a preliminary demand. For instance, donation of vaccines by industry, founders and international organizations prompted by the US President in March 2000 who announced new partnerships to develop and deliver vaccines for diseases including human immunodeficiency virus (HIV)/acquired immunodeficiency virus (AIDS), malaria and tuberculosis for developing countries (Table 4). It was announced that the US President would work with the G7 partners to ensure a future market for the critically needed vaccines (www.usinfo.stste.gov). Merck was to collaborate with Global Alliance for Vaccines and Immunization (GAVI) to identify countries that benefit from the Hepatitis B vaccine. Fisher (2000) pointed out that the proponents of mass vaccination and vaccine makers find ways to finance the delivery of newer and more expensive vaccines to poor countries by first making them as mandatory in rich countries. In some developed countries, vaccination was made mandatory for getting primary education.[46] On the one hand, the government-led vaccinations promoted the need for vaccine use, vaccine R&D and production. On the other hand, technology developments and government enforced vaccinations led to the burgeoning chemical/pharmaceutical industries in France, Germany and Britain. For instance, the Pasteur Institute founded in 1887 by the famed inventor of the rabies vaccine, eventually created Canada's largest vaccine manufacturer, Pasteur Merieux Connaught. Some argue that UNICEF launched a massive publicity drive to market the social product of child survival[47] and social marketing became the hallmark of the global child health programme.[48]

Table 4: Donation of Vaccines by Companies to Promote Vaccines and Vaccination

Manufacturer	Vaccine Donated/ Objective	Donation worth $s
Merck & Co.	Recombivax	$100 million
American Home Products Corporation	Hemophilus influenza type B to Global alliance for Vaccine Immunization (GAVI)	100 million doses
Glaxo SmithKline Beecham	To eliminate lymphatic filariasis	1 billion
Aventis Pharma	Polio vaccine to Africa	50 million doses
Merck & Co	Announced projects	more than $150 million
United States President	Announced to GAVI	$50 million
World Bank	To expand immunization	$400 million
other multinational banks	To expand immunization	$900 Million
Bill and Melinda Gates Foundation	to GAVI	$750 million

Source: Times of India, 3 March 2000.

Impact of Global Alliances and Initiatives on Vaccine Development in India

As described earlier in this paper, Indian vaccine development and immunization policies have mostly been prompted by global or transnational initiative of some form or other. This is also true of the recent global initiatives mentioned above. India hosted one of the meetings of the global programme on vaccination meant to promote the concept of global coalition for vaccine development and immunization. The meeting was held in New Delhi in 1998 and had participants from India, Pakistan, Bangladesh, World Bank, WHO, UNICEF and Indian industries.[49] Other meetings were held in the United States, Europe and Africa in the same year. Following the global trend, the Indian government launched an ambitious project to develop and manufacture new 'home grown' vaccines against several communicable diseases (malaria, tuberculosis, cholera, rabies, Japanese encephalitis and acquired immune deficiency syndrome (AIDS) in 3 years for $4 million. Twelve basic research institutions and two private companies (Hyderabad-based Indian Immunologicals and Bharat Biotech) have been brought together in a collaborative effort to develop and manufacture vaccines.[50] For the first time, the Indian government has allocated funding specifically for vaccine R&D. It is to be seen if this public-private initiative would ensure availability/affordability of future vaccines in public health programmes.

The Government of India launched the National Jai Vigyan Mission on development of new generation vaccines through DBT five years back. The objective of the programme is to generate candidate vaccines. The programme has been grouped under three categories. Category A includes candidate vaccines that require clinical trials (e.g. cholera, rabies), B category includes those vaccines whose efficacy and immunogenicity need to be worked out (e.g. tissue culture based Japanese encephalitis vaccine, DNA (Deoxy-ribose nucleic acids) vaccines, synthetic candidate malaria vaccine) and category C includes these vaccines, requiring sustained R&D efforts with the possibility for the development of candidate vaccines (e.g. Anti-HIV and DNA vaccines for TB).

While the above examples reflect the government's efforts to step in line with global trends of shifting the focus on vaccines from public sector to the private and transnational sector, the Indian industry has raised its pitch in asking for more. The All-India Biotechnology Association (AIBA), a forum of biotech companies, brought out a report in November 2000 after world wide consultation with experts from World Bank, Harvard University, etc., which was the first ever industry feedback on the Indian governments' biotechnology programme. The *All-India Biotechnology Association Report* alleged that the Indian biotech industry failed to deliver competitive biotech products due to the stringent regulatory system, lack of transparency that has stifled private sector investment, and this trend may dissuade foreign agencies from collaborating with Indian companies. It called for a fundamental restructuring of the regulatory system, as well as more resources for the private sector. The All-India Biotechnology Association approached the Technology Development Board of the Indian Union Ministry's Department of Science and Technology (DST), which was set up 5 years ago to provide loans to industries that have promising products to bring to the market. The Department of Science and Technology has applied for a loan of $ 100 million from the World Bank at the request of All India Biotechnology Association and $ 47.5 million would be used by the Department of Science and Technology to set up technology parks in India. The Finance Ministry was yet to approve of the World Bank loan.[51] This instance reveals how industry puts pressure on the governments to protect its own interest and how pressures from international organizations such as World Bank, etc., indirectly flow into national policies through the private industry.

Concluding Remarks

Vaccine R&D in India is as old as the history of vaccine itself, and India had the unique advantage of being one of the pioneers in developing vaccines against tropical diseases. However, the institutionalization of vaccine research in India and its trajectory of development over a century reveals that transnational factors shaped the research patterns, and very often, transnational interests had their impact on local factors and the national agenda. During the colonial period, the mercantile interests of the East India Company shaped the process of vaccine R&D and innovation in India.[52] Even though the institutions of the colonial period did R&D that led to the discovery of new vaccines and other important innovations in vaccines, increased demand for routine production functions with no division of labour to focus on research activity, and the limitations associated with institutional procedures for recruitment and career growth could not lay a path for a sustainable innovation process[53] even after independence.

During the initial decades of the post-independence period, vaccine was not the mainstay of Indian public health policy agenda, and international initiatives often shaped the pattern of vaccine research, production and immunization policies (Annexure 2). Also the regular use of primary vaccines for large-scale immunization and efforts to promote vaccine R&D in independent India was mainly shaped by a global agenda and the declaration of 'Health for All by 2000 AD' by the World Health Organization in 1978. However, consistency in the effort to implement the policy objectives were not maintained by successive Indian governments and wavered according to the socio-political situations of times. In the 1970s, there was a massive drive for an increase in the public sector role during Indira Gandhi's prime ministership, resulting into the emergence of more public sector units. Several private sector units were converted into public sector units. However, during the 1990s owing to liberalization the same public sector units were closed down. These included the new public sector units that were specifically aimed to produce primary vaccines using new technologies.

Thus, by the time the biotechnology revolution began in the world and universal vaccination became a global agenda, the Indian vaccine system lost nearly all the advantages of its early institutionalization, and was not sufficiently prepared (nor supported) for a revival through biotechnology, thereby setting the stage for technological obsolescence and import dependence. In addition, during the post-biotechnology period, the interests of transnational corporations/international organizations shaped the research pattern and production pattern of vaccines in India through industrialized countries or through international agencies. Considering the fact that vaccination became a national slogan only as a part of the international slogan, the Indian efforts to promote vaccine R&D were also in line with the international trends, notwithstanding the occasional nationalist pronouncements towards 'achieving self-sufficiency in vaccine production and self-reliance in vaccine technology' by AD 2000. As global trends in the post-biotech period increasingly led to shifting of the vaccine focus from the public sector to the private sector, India too was expected to follow suit. This seems to be the case with the failure of indigenous efforts to achieve self-reliance in OPV described earlier in this paper. The various questions raised in that context certainly provide some important links between international factors and the local policies, though there is no unambiguous evidence to establish a cause and effect relationship.

Similarly, the economic policies of liberalization and globalization promoted by the international agencies on the ground that they bring in investments and technology, seem to have achieved precisely the opposite result in the case of the measles vaccine at IVCOL: The closure of the Indian public sector company for non-availability of technology from its French public sector partner, due the privatization of the latter. The policies of liberalization and globalization implemented in India since 1991 under pressure from the World Bank and International Monetary Fund led to the marginalization of the public sector and allowed easy entry to foreign companies. It is no coincidence that around the same time, large TNCs in the West were seeking newer markets to release their biotech products. Moreover, markets for new vaccines were created through indirect means by lobbying for their inclusion in the national immunization programmes. Sometimes, the introduction of new vaccines in national immunization programmes was also articulated through bilateral R&D programmes, such as the Indo-US VAP. The case of Hepatitis B in India illustrates how its introduction in EPI overburdens the national governments and how the local realities such as disease incidence, endemicity and local priorities of vaccination have been over looked while considering the introduction of Hepatitis B into EPI.[54] Many western countries have included many other new vaccines (influenza type B, meningitis, influenza type b, MMR, chickenpox, etc.), in their regular immunization programmes.[55] In India too, soon there would be pressure to include many more vaccines in the EPI. Dr Plotkin who developed the vaccine against Rubella recommended that India should adopt this vaccine in the EPI.[56]

Moreover, dependence on the UN procuring system to meet the EPI requirements may also create a sense of dependency and act as a disincentive to develop indigenous capabilities in developing countries, especially on the ground that they do not follow good manufacturing practices. The WHO encourages procurement of vaccines required for EPI through the UN system. In developing countries, most of the vaccines under the EPI are made available at cheaper prices through the UN procuring mechanism. At the same time, the UN procurement mechanisms reduce the competitiveness of vaccines produced in developing countries, and UN agencies have been openly discouraging indigenous development. The World Development Report 1993 suggests that it is more cost-effective for developing countries to continue to import vaccines through UN mechanisms than to invest in vaccine manufacturing plants, especially since quality control and regulatory mechanisms are sub optimal in many developing countries.[57] However, the problems that may arise from dependence on the developed countries should not be ignored.[58] It is also important to re-examine the whole issue of uniform global standards for quality control, namely, the GMP and GLP adopted by international agencies, and whether these are realistic, practical and truly objective and unbiased. Otherwise, they can be a convenient (and easily convincing) means of excluding new, especially developing country companies or those from politically unfavoured nations from supplying to the UN procuring system, which is presently monopolized by a handful of Western TNCs.

Thus, while international agencies determine the global agenda for vaccination and support developing countries in implementing their programmes, they do not support indigenous capability development for vaccine production, or in other forms of preventive health. The findings reported in this paper are in line with others, which indicate that the global initiatives tend to influence the priority setting in developing countries, as well as increase import dependence.[59] As argued by Banerjee (1996), the ruling classes in western industrialied countries have long used access to health services as a means of perpetuating their social and economic control over the peoples of the third world.

The Indo-US VAP was signed initially for five years, was later extended by five more years in 1992 and the programme continues till date (see annexure 1 for details). In the initial stages, the Indo-US VAP chose mutual interest research projects such as, viral hepatitis, hepatitis

Non A Non B, rotavirus diarrhoea, *E. coli* diarrhoea, typhoid, improved pertussis vaccine, canine rabies, respiratory syncytial virus and poliomyelitis. Initially, projects on Hepatitis Non A Non B, cholera, poliomyelitis and typhoid were approved. Tuberculosis, which was the top most killer among the vaccine preventable diseases was added only in 1995-96. Till 1998-1999 around 19 projects were approved and around 20 new proposals were under consideration. A new project was initiated on the development of edible vaccines in transgenic plants (tomato) against dairrhoea and cholera (DBT *Annual Report 1999-2000*). Thirteen years after launching the Indo-US VAP, the outcome of the projects revealed that, so far diagnostic kits for kala-azhar, hepatitis C and tuberculosis are being developed. Two candidate rotavirus vaccine strains were developed and patents were filed in the US by the Indian Institute of Science (IISC) Bangalore (1321 strain) and by All India Institute of Medical Sciences (AIIMS), New Delhi (116E). The rotavirus 116E strain was found to be immunogenic in newborn babies in AIIMS. Both candidate vaccines were tested in phase I trials in Cincinnati, US, and steps have been initiated to conduct phase I clinical trials in India.[60]

Diarrhoea is mainly caused by *E coli* in India (Brown et al. 1988, Ghosh et al. 1991) and rotaviral diarrhoea is not very significant, according to the ex-director of National Institute of Virology, Pune. However, candidate vaccines have been developed and are undergoing phase I trials (Annexure 1). While one does not underestimate the importance of development of diagnostic kits, it is interesting to note that under the Indo-US VAP, more diagnostic kits are being developed when compared to vaccine development. The development of diagnostic kits take a shorter time when compared to the development of vaccines and, therefore, reach the market early. An objective analysis of the prevalent disease pattern based on health surveillance information would have helped to identify more appropriate research priorities in India. However, owing to collapse of the surveillance system in India, this exercise may not be very meaningful. While the World Bank earlier gave funding to improve the Indian surveillance system, later it withdrew the same.[61] While the progress in research collaboration under the Indo-US VAP may be genuine, the real conflict may come up when ownership and patents of technology issues arise if it develops new vaccines and generates vaccine innovations.

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Annexure 1: Projects under Indo-US Vaccine Action Programme

Project	Approved in the year	Indian Collaborator	American Collaborator	Duration & Out come
Etiological & biological studies on enterically transmitted NANB hepatitis	1988-89	National Institute of Virology (NIV), Pune	Hepatitis virus section, National Institute of Health (NIH), Bethesda	5 years (New knowledge generated to develop a diagnostic kit)
Antigenic properties of *vibrio cholerae*	1988-89	Central Drug Research Institute, Lucknow	Centre for Vaccine Development, Baltimore, USA	3 years (molecular characterization confirm immunogenic properties of antigen)
Diagnosis of typhoid fever	1988-89	Christian Medical College (CMC), Vellore	Texas University Health Sciences, Texas	4 years (Field trials of ELISA based kit in CMC, Vellore was tested)
Neurovirulence & attenuation of poliovirus in primates	1988-89	Christian Medical College, Vellore	University of Colorado, Health science Centre, Denver	4 years (three mutant type-1 polio were developed and being tested for development of vaccine)
Molecular expression of human rotaviral genes	1989-90	Department of Microbiology and Cell Biology, IISC, Bangalore	School of Medicine, Stanford University, USA	5 years (neonatal rotaviral candidate vaccine 1321 was developed and conducted phase I trials in USA)
Characterization of AIIMS neonatal rotavirus strain as a vaccine candidate	1990-91	All India medical Institute (AIIMS), New Delhi	Viral Gastroenteritis unit, Centre for Disease Control (CDC), Atlanta	5 years (rotaviral candidate vaccine 116E was developed, tested in newborns in AIIMS and conducted phase I trials in USA)

Annexure 1 continued

Annexure 1 continued

Project	Approved in the year	Indian Collaborator	American Collaborator	Duration & Out come
Diagnosis of diarrohegenic *E coli* and development of ETEC vaccine against diarrhoea	1990-91	National Institute of Communicable and Enteric Diseases (NICED), Calcutta	John Hopkins University, United States of America (USA)	5 years (a diagnostic kit was developed for its use in India)
Etiology and diagnosis of NANB viral hepatitis	1990-91	All India Medical Institute (AIIMS), New Delhi	Hepatitis virus section, NIH, Bethesda	3 years (New finding: hepatitis E as the major cause of severe sporadic hepatitis in endemic area)
Molecular characterization and immunodiagnosis of Hepatitis C	1991-92	Osmania Medical College, Hyderabad	University of Colorado, Health science Centre, Denver	3 years (developed a method for detecting Hepatitis C virus by PCR technique)
Evaluation of ARI organisms to develop vaccines	1991-92	JIPMER, Pondicherry	John Hopkins University, USA	Diagnostic kit being prepared for some ARI organisms
Characterization of *E. coli* pathogen	1991-92	AIIMS, New Delhi	Pennsylvania State University	Molecular characterization being carried out
Plasma derived Hepatitis B vaccine Production	1992-93	BIBCOL, Bulandshar	CDC, Atlanta	Under progress
Site preparation evaluation vaccines for prevention of typhoid	1995-96	AIIMS, New Delhi, Tuberculosis Research Centre, Chennai	NIH, Bethesda	

Annexure 1 continued

Annexure 1 continued

Project	Approved in the year	Indian Collaborator	American Collaborator	Duration & Out come
The development of edible vaccines in transgenic plants (tomato)	1998-99	Delhi University, South campus, CBT, NII, New Delhi Delhi, IMTECH Chandigarh		
Diagnostic kit for hepatitis	1998-99	RGCB, Medical Deccan college, Trivandrum	University of Colorado	Commercial kit is being developed
Diagnostic kit for kala-azar	1998-99	JNU, New Delhi		A diagnostic kit is being developed
A diagnostic kit for TB	1998-99	AIIMS, New Delhi		A diagnostic kit is developed and a patent has been filed
20 more proposals are under consideration	1999-2000			

Source: DBT Annual Reports 1987-88 t0 1999-2000.

ARI: Acute respiratory infections, TB: Tuberculosis, PCR: Polymerage chain reaction, CBT: Centre for Biotechnology, JNU: Jawaharlal Nehru University, NII: National Institute of Immunology, IMTECH: Institute of Microbiol Technology, RGCB: Rajiv Gandhi Centre for Biotechnology, NANB: Hepatitis non A and non B, ELISA: Enzyme linked immuneabsorbant assay, IISc: Indian Institute of Sciences, JIMPER: Jawaharlal Nehru Institute of Post Graduate Medical Education and Research, BIBCOL: Bharat Immunologicals and Biologicals Ltd.

Annexure 2: Events related to Health Planning in India and in the World

1947	Ministries of Health were established at the centre and states in India. The posts of Director General, Indian Medical Science and of Public Health Commissioner with the Government of India were integrated in the post of Director General of Health Services, who is the principal adviser to the union government on both medical and public health matters.
1948	Formation of World Health Organisation (WHO) to establish a single worldwide intergovernmental health agency. India joined the World Health Organization as a member state.
1949	The South East Asia Regional office of the WHO was established in New Delhi. The Indian Research Fund Association was reconstituted into Indian Council of Medical Research (ICMR).
1950	The Planning Commission was set up by the Government of India.
1951	The beginning of the First Five Year Plan in which 5.9 per cent out of total outlay was allotted to health programmes.
	The BCG vaccination programme was launched in the country.
1953.	The National Malaria Control programme was commenced as part of the First Five Year Plan. A nationwide Family Planning programme was started.
1960	The School Health Committee was constituted by the Union Health Ministry to asses the standards of health and nutrition of school children and suggest ways and means to improve these.
1965	Direct BCG vaccination without prior tuberculin test, on a house-to-house basis was introduced.
1966	Ministry of Health, Government of India was constituted to look into the additional staff required for primary health centres and to maintain the work of malaria and smallpox control programmes.
1974	WHO established the Expanded Programme on Immunization (EPI) to protect children against tuberculosis, measles, diphtheria, whooping cough (pertussis), tetanus and polio.
1978	WHO adopted the goal of 'health for all' by AD 2000, challenged the countries of the world to provide immunization services to all children or UCI by year 1990.
	Expanded Programme on Immunization (EPI) was launched by Government of India. Declaration of Alma Ata underlined the primary health care approach.
1979	World Health Assembly endorsed the declaration of 'Alma Ata' on primary health care.

Annexure 2 continued

Annexure 2 continued

1980	World Health Assembly declared eradication of small pox from the entire world.
1981	WHO and Member countries adopted the Global Strategy for Health for All. Report of the Working Group on Health for All, setup by the Planning Commission was published.
1982	The Govt. of India announced its National Health Policy. A Biotechnology Board was formed. UNICEF launched Child Survival and Development Revolution-immunization along with other cost effective, high impact interventions in its 'GOBI-FFF' package.
1984.	Task Force for Child Survival' launched by UNICEF, WHO, UNDP, World Bank and Rockfeller Foundation for international coalition to increase international collaboration.
1985.	United Nations general assembly affirmed full support for the goal of UCI 1990 and 74 countries and 400 voluntary agencies pledged to achieve the goal by 40th Anniversary of United Nations. Technology Mission was launched by Ministry of Heath and Family Welfare and DBT was a nodal agency to implement EPI programme in vaccines in India.
1986	Department of Biotechnology (DBT) was established in India.
1987	A world wide "safe motherhood" campaign was launched by World Bank.
1990	The World Summit for children convened in New York announced ambitious goals for 1990s.
1992	Child survival and safe motherhood programme (CSSM) was launched on 20 August.
1995.	ICDS renamed as Integrated Mother and Child Development Services (IMCD)
1996.	Pulse polio immunization took place on 9 December and 20 January 1996. The second phase of PPI conducted on 7 December 1996 and 18 January 1997.

Source: Compiled from Park & Park (1997), Banarasidas Bhanot Publishers, Delhi, and "Vaccination and World Health" by Cutts, F.T. (1994) John Wiley & Sons Ltd., London.

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GM Cotton in Gujarat: General Madness or Genuine Miracle?

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Abstract: Genetically modified crops are the latest contribution to agriculture from modern plant biotechnology. As food security at a reduced cost and the promised of an assured crop has always attracted the attention of farmers and the State, genetically modified cotton or Bt cotton cultivation which meets these expectations is spreading steadily in developing countries. Farmers are willing to adopt this technology to reduce the pest attack and cost of cultivation and thereby improve the yield. India has also approved the commercial cultivation of the Bt cotton since 2002. There are a number of studies carried out by NGOs, independent researchers as well as some that are company sponsored, either for or against the Bt technology. Nevertheless, a uniform conclusion does not emerge from these studies about the performance of Bt cotton. Gujarat was one of the few states where genetically modified cotton was officially introduced in 2002. The unapproved Bt cotton by then had already entered the cultivation scheme of the farmers. A survey conducted in 2002 compared the performance features of the approved and unapproved varieties of cotton among farmers. The study showed that an equal number of acres were under the unapproved variety. While there are unresolved questions about the pest resistance capacity of the approved variety itself, the fast spread of the unapproved variety causes more concern. A detailed regulatory framework has been set up to regulate and monitor the research and open field trials of genetically modified organisms. However, it is evident that the reverse order information flow from the bottom to top layers of the framework is lagging so that this results in a flourishing sale of the unapproved variety and a lack of compliance with the biosafety regulations. This situation would actually lead to the technology loosing its potency sooner than it is expected leaving the farmers to look for a newer way out.

Keywords: Approved Bt, unapproved Bt, farmers, biotechnology, regulation, environment, pesticide

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Introduction

Biotechnology refers to the manipulation of living organisms for scientific or industrial use. The 'modern' biotechnology refers to a set of techniques such as genetic engineering, cell and tissue cultures, protein synthesis and enzymology. This is different from the earlier technologies involved in making bread, vaccines and antibiotics as it involves the manipulation of the original traits or gene of an organism. Such genetic manipulation can be to: (a) alter the genes already functioning within an organism; (b) transfer a gene from one organism to another organism of the same species and (c) transfer a gene from one organism to an organism of a different species. This type of genetic modification is known as resulting in genetically modified organisms (GMO) or *transgenic* because it cuts across species and plants. In agriculture, it can be expected to benefit developing countries by for example (a) increasing productivity; (b) reducing vulnerability due to the whims of nature and on slaughts of pests, and (c) improving the nutritional quality of the food. The area under GM crops is steadily increasing in many parts of the world - from 1.7 million hectares in 1996 to 58 million hectares in 2002.

However, such GMOs in plants have evoked a mixed response from agriculturalists and environmentalists since the concern is not only to improve agricultural productivity but also to sustain the natural resources and protect the environment in the process. In India also, the area under genetically modified cotton crop is increasing in spite of a strong lobby against the entry of GM crops in the country. The protest in India forms part of an international environmental movement against GM crops in general. There have been allegations and counter allegations of suppression of facts that reveal the possible positive and negative impacts. There are questions of economic gains both short-term and long-term and the environmental and ecological sustainability of introducing GM crops. There are two types of argument that are made.

One set deals with the insincerity and inadequacy on the part of the regulatory mechanisms that have been constituted and the working of these. This argument has its basis in the belief that the developing countries are not generally equipped to handle the testing and regulation of innovative technological breakthroughs that claim a tremendous potential to bring revolution in the sector or sub sector. It is thus, implicitly assumed that technological breakthroughs and their potential do not have any intrinsic problem, but the operationalization and regulation of these is problematic and hence such technologies should not be brought in without adequate preparedness. The second set of arguments raise doubts about the potential of the technology to help humanity in reducing poverty and in increasing material welfare. Environmentalists all over the world use both types of arguments to attack the possible propagation of new technologies such as the GM seeds. In India, the commercialization of GM cotton was allowed only in 2002 in a few states, which has raised a series of issues ranging from the validity of the field trials to the performance of GM cotton in the country. While these issues by and large remain unanswered, the unapproved GM cotton is being cultivated in most of the cotton growing states.

This raise issues such as: (a) what kind of regulatory framework do we have in India to monitor such new technologies; (b) the type of intellectual property protection offered to plant varieties and the GM cotton in question; (c) why farmers prefer to use unapproved variety of cotton, and (d) what are the implications of the spread of unapproved variety in India? Some of these issues warrant attention and discussion. We attempt to seek answers to some of these questions in this paper. The paper is organized as follows. In the section that follows the introduction, we discuss the regulatory framework that exists in India for the promotion and monitoring of biotechnology. In the third section we discuss the intellectual property protection offered to plant varieties. In the following section we compare the performance of the approved and unapproved variety with the help of data that were collected from a survey among selected farmers in Gujarat. In the final section, a few comments are made on the present scenario and its likely fall out in future on GM cotton as well for as other GM crops.

Regulatory Framework for Plant Biotechnology in India

Both developed and developing countries have put in place certain guidelines for the research, trials and cultivation of GM crops. India is a signatory to the Convention of Bio diversity and has also signed and ratified the Cartegena Protocol (CP) on biosafety. Therefore, India is committed to establish or maintain means to regulate manage or control the risks associated with the use and release of GMOs, which are likely to have adverse environmental impacts and affect the conservation and sustainable use of biological diversity. Hence a detailed legal and institutional framework governing GM crops has been set up in view of the fact that a number of trials are going on in the private and public sector. It appears that India perhaps adopts the concept of familiarity and a product based approach in approving the commercial release of a GM crop. As per the concept of familiarity, the possible risk characteristics of the GM crop are studied in comparison with the non-GM crop. The product based approach ensures that all plants and the product with new characteristics not previously used in agriculture or production are monitored irrespective of whether they contain a GM trait or not.

GMOs are regulated in India under the purview of Environment Protection Act, 1986. The objective of this Act is to protect the environment, nature and health in connection with the application of genetic engineering in producing GMOs. The 1989 Rules for the 'manufacture, use, import, export and storage of hazardous micro organisms, genetically engineered organisms or cells' were subsequently revised in 1994 and 1998. These rules mandate the creation of six competent authorities that are in charge of lab experiments, field experiments and the commercial release of GMOs as mentioned below:

(i) Recombinant DNA Advisory Committee (RDAC) is mandated to evolve the Recombinant DNA safety guidelines. RDAC also reviews biotechnology developments at the national and international levels and recommends suitable biosafety regulations for India.

(ii) Review Committee on Genetic Manipulation (RCGM) functions under the Department of Biotechnology and includes representatives of: Department of Biotechnology (DBT), Indian Council of Medical Research (ICMR), Indian Council of Agricultural Research (ICAR) and Council of Scientific and Industrial Research (CSIR). Functions of the RCGM include the issuing of guidelines for GMO research, authorizing rDNA projects in high-risk category and controlled field experiments and permitting imports of GMOs for research.

(iii) Genetic Engineering Approval Committee (GEAC) functions as a body under the Department of Environment, Forests and Wildlife and comprises of: (a) Chairman-Additional Secretary, Ministry of

Environment and Forests, (b) Co-chairman – a representative from the Department of Biotechnology, (c) Representatives from the Ministry of Industrial Development, (d) Departments of Biotechnology and Atomic Energy, (e) Indian Council of Medical Research, (f) Council of Scientific and Industrial Research, (g) Directorate of Plant Protection, and (h) Central Pollution Control Board (CPCB). The functions of this Committee are to: authorize commercial use (including import) of GMOs or their products; authorize large scale production and release of GMOs and their products into the environment; and mandate restrictions or prohibitions on production, sale, import or use of GMOs, if necessary.

iv) State Biotechnology Coordination Committee (SBCC) should be established as per the guidelines, in states where research or experiments with GMOs is going on. The Committee comprises of: the Chief Secretary of the State Government; Secretaries from the Departments of Environment, Health, Agriculture, Commerce and Forests, Public Works, Public Health; Chairman, State Pollution Control Board; and state microbiologists and pathologists. The functions of the SBCC is to: periodically review safety and control measures in institutions handling GMOs; inspect and take punitive action in case of violations through the State Pollution Control Board or Directorate of Health; act as nodal agency at the state level to assess damage if any from the release of GMOs and to take on-sight control measures.

(v) District-level Committee (DLC) is required to be established in the districts wherever GMO trials or research is going on. The DLC should comprise of: District Collector, Factory Inspector, Pollution Control Board Representative, Chief Medical Officer, District Agricultural Officer, Public Health Department Representative, district microbiologists/pathologists, Municipal Corporation Commissioner. The functions of the DLC are to: monitor safety regulations in installations; investigate compliance with rDNA guidelines and report violations to SBCC or GEAC; act as nodal agency at the district level to assess damage if any from release of GMOs.

(vi) Institutional Bio safety Committee (IBSC) should be established by every institution engaged in GMO research. This should consist of the head of: the organization, scientists engaged in rDNA work,

> the biosafety or Medical Officer and a nominee from the Department of Biotechnology. The functions of this committee are to: oversee rDNA research activities; seek approval of the RCGM for category III risk experiments- experiments on transgenic traits which on release into the environment may cause significant alterations to the biosphere, ecosystem, plants and animals; ensure adherence with bio safety guidelines; prepare an emergency plan for exigencies that could arise; and keep the District Level Committee, State Level Biotechnology Co-ordination Committee and GEAC informed about relevant experiments.

The above framework shows that regulatory authorities have been set up with specific responsibilities at the central, state and district level indicating a top down approach. Such an approach necessitates that after the commercial release of the GM crops, the reverse order flow of information from the district to the central government has to be there to ensure that regulating guidelines are complied with and for monitoring of GM crops. This is very essential to ensure that the appropriate procedures are followed prior to and after the open release of GMOs.

Intellectual Property Protection for Plants

Traditionally most biological research in the field of agriculture was kept outside the arena of intellectual protection because, these biological entities have the ability to reproduce themselves, which made it difficult to enforce property protection. But providing intellectual property rights was in practice for plant species like flowers, fruits and vegetables that could be bred and do not reproduce by conventional and natural methods. In the recent past, there has been huge investment-intensive research in agricultural crops as well in the private sector of the developed countries. According to an estimate, private investment in biotechnology research ($5billion) is far ahead of the public investment in developed countries. In comparison to this, there is hardly any private investment in the developing countries and the public investment in biotechnology is around $125 million. The western countries, particularly the US, lead the rest of the world in plant biotechnology followed by Europe and Japan. The business and research environment prevailing in these countries supported by strong intellectual property protection has enabled these countries to march ahead of other countries.

Patents, plant breeders' rights, trademarks, geographical indications and trade secrets can protect innovations in agriculture. Besides this the Union Internationale pour la protections des Obtentions vegetables (UPOV), a multilateral treaty which is administered in cooperation with the World Intellectual Property Organization (WIPO), is also adopted by several countries.

India has however developed a *sui generis* system, which is weaker than the patent system after nearly a yearlong debate on the draft bill on Indian Plant Varieties and Farmer's Rights Bill in 2001. The highlights of this IPVRB are: (a) Varieties will be granted protection on the basis of novelty, distinctness, uniformity and stability. (b) The distinctness of a variety is recognized if the said variety is distinguishable by at least one essential characteristic from any other variety whose existence is common knowledge in any country at the time of filing the application. (c) Registration under this Act shall confer an exclusive right on the breeder or his successor, his agent or licensee to produce, sell, market, distribute, import or export the variety. (d) A farmer shall be deemed to be entitled to save, use, sow, resow, exchange, share or sell his farm produce including seed of a variety protected under this Act in the same manner as he was entitled before the coming into force of this Act. However, a farmer will not be entitled to sell branded seed of a variety protected under this Act. A protected variety can be used for conducting experiment or research. But if an initial source of a registered variety is repeatedly used for the purpose of creating other varieties for commercial production, then authorization of the breeder of the registered variety is required.

The important aspects in which the Indian Act scores merit over UPOV or patent protection is that the distinctiveness criterion requires that the variety seeking protection is to be distinguishable from other variety by at least one essential characteristic. Second, the extent of protection provided to the breeder stops at the right to produce, sell, market, distribute, import or export the variety and does not extend to harvested material and other products obtained from material of the variety. That is, for instance, Monsanto cannot claim right over the harvest from the protected seed, which can be used by the farmer for subsequent cultivation. It may be noted that most non-European legislation including that of the US allows farmers to save seeds of protected varieties. However, European legislation is more stringent on this. Under arrangements between EU farmers and breeders all farmers have to pay royalty even when they use farm-saved seed of protected varieties, though the royalties are lower than those for commercial seed. This restriction greatly increases the revenue a breeder can derive from marketing a new protected variety.[1]

In India, the IPVRB will be implemented by the Plant Varieties and Farmer's Rights Protection Authority. Whereas the original Bt gene of Monsanto is protected in the US, companies seeking introduction of this gene have to obtain a license from Monsanto and get an approval from the GEAC for introducing the same in India. It may be noted that though it is not possible to get a plant patent in India, 'patents are possible for many aspects of a plant and its utilization except the plant per se. Inventors have to look for multiple protection and not just think in terms of protecting plant per se' (*IPR Bulletin*. September 5, 2004).

'In India, 484 applications have been filed specifically referring to plants since November 1994 till December 2003. Of these 484 applications, 221 are convention applications and 265 are non-convention applications. The convention applications also include 132 PCT applications out of which 72 relate to plant extracts and 60 relate to various compositions from plant products. The major applicants are CSIR, Avestha Gengraine Tech (19), JB Chemicals and Pharmaceuticals Ltd (11) and Synit Drugs Pvt. Ltd (10). 109 applications were filed in 2001 and 70 were filed in 2002' (*IPR Bulletin*, Sept, 2004).

This Bulletin also reports that the CSIR obtained a plant patent from the USPTO in August 2001 for a new hybrid variety of mint or mentha claiming priority from June 03 1998. The invention relates to a new and distinct interspecific hybrid mint plant called 'Neerkalka' which is developed by asexual crossing between improved Mentha arvensis and pollen plant mentha spicata. Nevertheless, the research that is going on in both the private and public sector in India (Tables 1 and 2) necessitates an appropriate plant protection system in place for India.

Table 1: Major Developments in Transgenic Research and Application in Public Sector

Institute	Plants/Crops	Transgene(s) inserted	Aim of the project
AAU, Johat, Assam	Chickpea	Bean alpha AI	To generate plants resistant to bruchids
Bose Institution Kolkata	Rice	S-adenosylmetbinine decarboxylase	To generate plants tolerant to stress
Central Institute for Cotton Research, Nagpur	Cotton	Bt. Cry gene(s)	To generate plants resistant to lepidopteron pests
Central Potato Research Institute, Simla	Potato	Bt. Cry1A(b)	To generate plants resistant to lepidopteron pests
Central Tobacco Research Institute, Rajahmundry	Tobacco	Bt. CrylA(b) and cry IC	To generate plants resistant to Helicoverpa armiger and Spodoptera litura
Centre for Cellular and Molecular Biology, Hyderabad	Rice	Bar	To generate herbicide-tolerant plants
Central Rice Research Institute, Cuttack	Rice	Bt. CryIA(b) Xa21	To develop plants resistant to lepidopteron pests, bacterial blight/disease
Delhi University, South Campus, New Delhi	Mustard/ rapeseed	Bar, barmase, borstar	To generate herbicide-tolerant plants, male-sterile and restorer lines for hybrid seed production
	Rice	Pyruvate decarboxylase and alcohol dehydrogenase	To generate plants tolerant to flooding
	Tomato	Ctx-B and Tep antigens of Vibrio cholerae	Edible vaccine development

Table 1 continued

Table 1 continued

Institute	Plants/Crops	Transgene(s) inserted	Aim of the project
	Brinjal	Chitinase, glucanase and thaumatin encoding genes	To generate plants resistant to diseases
	Cabbage	Bt. CryIA(b)	To generate plants resistant to lepidopteron pests
	Wheat	Bar, HVAI, PIN2	Resistance against biotic and abiotic stresses
	Rice Pusa basmati	Cod A, Cor 47,	Resistance against biotic and abiotic stresses
Directorate of Rice Research, Hyderabad	Rice	Xa-21, cry 1 A (b)	To generate plants resistant to lepidopteran pests and bacterial and fungal diseases
Indian Agricultural Research, Institute, New Delhi	Brinjal	Bt. CryIA(b)	To generate plants resistant tolepidopteron pests
	Cauliflower	Bt. CryIA(b)	To generate plants resistant to Pluella scylostella
	Tomato	Bt. CryIA(b)	To generate plants resistant tolepidopteron pests
	Cabbage	Bt. CryIA(b)	To generate plants resistant to P scylostella
	Rice	Bt cry 1A(b), Chitinase	To generate plants resistant tolepidopteron pests
	Mustard/ rapeseed	Arabidopsis annexin gene	To generate stress-tolerant plants
	Mustard/ rapeseed	Choline dehydrogenase	To generate abiotic stress-tolerant plants

Table 1 continued

Table 1 continued

Institute	Plants/Crops	Transgene(s) inserted	Aim of the project
	Potato	ACC synthase	To control fruit ripening
	Tomato	ACC synthase	To control fruit ripening
	Banana	ACC synthase	To control fruit ripening
	Tobacco	Chitinase, glucanase and RIP	To generate plants resistant to fungal attack
	Brassica	Chitinase, glucanase and RIP	To generate plants resistant to fungal attack
	Pigeonpea	Protease inhibitor and lectin genes	To generate plants resistant to boll worms and aphids
IARI sub-station, Shillong	Rice	Bt. Cry1A(b)	To generate plants resistant to yellow stem borer
International Centre for Genetic Engineering Biotechnology, New Delhi	Tobacco	Bt.cryIIa5	To generate plants resistant to Spodop eratlitura
	Rice	Gm2	To generate plants resistant to gall midge
International Crop Research Institute for Semi-Arid Tropics, Hyderabad	Chickpea	PGIP	To generate plants resistant to fungal pathogens
Indian Institute of Horticulutral Research, Bangalore	Muskmelon	Rabies glycoprotein gene	To develop edible vaccines
	Tomato	Leaf curl virus sequence	To generate plants resistant to leaf curl, virus
	Tomato	Chitinase and glucanase	To generate plants resistant to fungal diseases

Table 1 continued

Table 1 continued

Institute	Plants/Crops	Transgene(s) inserted	Aim of the project
	Citrus	Coat protein gene of citrus triesteza virus	To develop transgenic citrus plants resistant to cirus triesteza
Jawaharlal Nehru University, New Delhi	Potato	Ama-1*	To generate nutritionally enriched plants
	Tomato	OXDC*	To generate plants resistant to fungal infection
Madurai Kamaraj University, Madurai	Blackgram	Dianhin and barmase gene or Bar	Development of insect resistant and herbicide-tolerant plants
	Blackgram	Coat protein and replicase genes of Vigna mungo yellow mosaic virus	To develop viral-resistant plants
	Rice	Chitinase, B-1,3 glucanase and osmotin genes	To develop plants resistant to fungal infection
	Coffee	Chitinase, B-1,3 glucanase and osmotin genes	To develop plants resistant to fungal infection
Narendra Dev University of Agriculture, Faridabad	Rice	Cry1A(b)gene	To generate plants resistant to lepidopteron pests, bacterial and fungal diseases
National Botanical Research Institute, Lucknow	Cotton	Cry1E and CryIC with terminal altered at C-end	To develop transgenic resistant to Spodopotera litura and Helothisis armigera
Punjab Agricultural University, Ludhiana	Rice Pusa basmati	Cry1Ab, Cry1Ac	For resistance against yellow stem borer

Table 1 continued

Table 1 continued

Institute	Plants/Crops	Transgene(s) inserted	Aim of the project
Tata Energy Research Institute, New Delhi	Mustard	Ssu-maize Psy and Ssu-tpCrt1 gene	To generate plants containing high levels of b-carotene
Tamil Nadu Agricultural University, Coimbatore	Rice	GNA gene	To generate plants resistant to pests gall midge
University of Agricultural Sciences, Bangalore	Muskmelon	Rabies glycoprotein gene	To develop edible vaccines

* Genes isolated in India. In most of the viral work, sequences for pest-derived resistance (PDR) have been isolated from the viral strains predominant in India

Source: www.iisc.ernet.in/currsci/feb102003/297.pdf

Table 2: Transgenic Lines in Advanced Stage of Development for Field Trials in Private Sector

Ankur Seeds Ltd., Nagpur	Cotton*	Cry1A (C)	To generate plants resistant tolepidopteron pests
Hybrid Rice International, Gurgaon	Rice	Cry1A(b), cry9(c) and bar genes	To develop plants resistant to lepidopteron pests and herbicide tolerance
Indo-American Hybrid Seeds, Bangalore	Tomato	Alfalfa glucomase and Tomato leaf curl virus genes	To generate plants resistant to viral and fungal attacks
MAHYCO, Mumbai	Cotton*	Cry1A©	To generate plants resistant to lepidopteron pests
	Cotton*	CP4ESPS	To generate plants for resistance to herbicide glyphousie
	Cotton*	CryX gene	To generate plants resistant lepidopteron pests
	Corn*	CrylA(b)	To generate plants resistant lepidopteron pests
	Pigeonpea	GUS	For transformation work
	Rice	CrylA©, Xa21 and GNA genes	To generate plants resistant to lepidopteron pests, bacterial blight and sucking pests
	Mustard	CP4 EPSPS	To generate plants tolerant to herbicide
MAHYCO Research Foundation, Hyderabad	Rice	Xa-21	To generate plants resistant to bacterial blight
Progo PGS (India) Ltd. Gurgaon	Brasical mustard	Bar, banase, barstar	To develop superior hybrid cultivars
	Tomato	CrylA(b)	To generate plants resistant to lepidopteron pests

Table 2 continued

Table 2 continued

	Brinjal	CrylA(b)	To generate plants resistant to lepidopteron pests
	Cauliflower	CrylH/Cry9C lepidopteron pests	To generate plants resistant to
	Cauliflower	Bar, Barnase, Barstar	To develop superior hybrid cultivars
	Cabbage*	Cryl 9C lepidopteron pests	To generate plants resistant to
Syngenta India Ltd., Pune	Cotton*	Vip 3 gene lepidopteron pests	To generate plants resistant to
	Maize*	CrylA(b) lepidopteron pests	To generate plants resistant to

Transgenics developed elsewhere are being backcrossed to inbred lines to develop commercially viable hybrids that can be grown in different agroclimatic regions of the country

Source: www.iisc.ernet.in/currsci/feb102003/297.pdf

Performance of GM Cotton in Gujarat

Cotton is an important commercial crop in Gujarat and farmers readily adopt hybrid cotton. A larger percentage of cotton falls under the unirrigated area. Like the rest of the cotton growing parts, frequent and intensive pest attacks have caused a severe set back to the cotton crop in Gujarat and farmers became indebted. Hence, any technological breakthrough promising lower pest attack and improved yield levels would be welcomed by the farmers of Gujarat. Table 3 reports that cotton cultivation on an average accounts for 15 per cent of the total area under cultivation in Gujarat. Whereas the area under cotton crop in the state increased from 1566 in 1980-81 (000 hectares) to 1750 in 2002, production declined from 1738 to 1703 followed by the declining trend in yield from 189 to 165. Moving averages indicate that whereas the area under cotton has stagnated after 1996-97, production has been inconsistent. The late 1990s is also the period when the cotton crop all over the country failed due to severe pests attack contributed by unseasonal rainfall in several places. This was the scenario at the time of introduction of GM cotton in Gujarat.

Chronology of Events Preceding Introduction of Bt Cotton

It may be useful to go through the chronology of events in the introduction of Bt cotton in India and Gujarat. In March 1995, the Department of Biotechnology, Government of India permitted an import of 100 grams of Transgenic Cocker - 312 variety of cottonseeds by Mahyco from the US. In April 1998, Monsanto entered into collaboration with Mahyco and got permission for undertaking small trials of 100 gm Bt per trial. In November 1998, thousands of farmers in Karnataka burnt down the Bt cotton trial field protesting against Monsanto. In January 1999, the Research Foundation for Science, Technology and Ecology (RFSTE) of New Delhi challenged the legality of the field trial permission granted by the Department of Biotechnology. In July 2000, permission was granted to undertake large-scale field trials including seed production at 40 sites in six states. The data, because of which the permission was granted, was kept confidential. However, it was inferred that the small trials showed that Bt Cotton was 'safe'. In January 2001, a ten member team from the US comprising of judges and scientists came and educated the Chief Justice of the Supreme Court of India on biotechnology. In June 2001, an

Table 3: Area, Production and Yield of Cotton in Gujarat 1980-81 – 2001-02

Year	Area in 000 Hectares	3 years Moving Average	Production in 000 tonnes	3 years Moving Average	Yield in 000 Bales of 170 Kg. each	3 years Moving Average	Area under Cotton as Percentage to total area under crops
1980-81	1566	-	1738	-	189	-	13.45
1985-86	1451	-	2122	-	249	-	13.16
1990-91	1042	-	1531	-	250	-	9.85
1991-92	1135	1109	1181	1567	177	240	16.08
1992-93	1151	1137	1988	1597	294	239	15.46
1993-94	1126	1197	1623	2044	245	289	10.74
1994-95	1313	1319	2522	2184	327	281	11.72
1995-96	1517	1457	2408	2583	270	303	13.86
1996-97	1542	1552	2819	2881	311	315	14.16
1997-98	1598	1604	3417	3413	364	361	14.55
1998-99	1672	1672	4004	3169	407	334	15.27
1999-00*	1539	1539	2086	2417	230	253	15.89
2000-01*	1615	1615	1161	1650	122	172	17.43
2001-02*	1750	-	1703	-	165	-	17.49

Source: Socio Economic Review Gujarat State, 2002-03.

open dialogue was held between Monsanto and Greenpeace to discuss Bt cotton with scientists, representatives of the Ministry of Environment and Forest and farmers. Field data was not shared in this meeting. In the same month, that is in June 2001, the GEAC approved large-scale trials and Mahyco conducted trials in 100 hectares in seven states.

Around September 2001, scientists from Mahyco observed that transgenic cotton was being grown at nearly 10,000 acres of Gujarat. It was reported that these farmers had purchased the seeds from Navbharat, a seed company, which is thought to have developed the seed as a hybrid from the transgenic seed, imported from the US. Since this large-scale plantation was done without GEACs permission, GEAC ordered the destruction of the crop.

In November 2001, Gene Campaign filed a case in Delhi High Court challenging the government with negligence in allowing large scale field trials conducted without appropriate monitoring, regulation and safety precautions. In February 2002, the Indian Council of Agricultural Research (ICAR) submitted a positive report to the MoEF on the field trials of Bt cotton. On 26 March 2002, India joined the GM community by giving a green signal for the commercial cultivation of GM crops. Three varieties of cotton using Monsanto's Bt technology got the approval. Two seasons have passed since and the third is in progress. Farmers in Andhra Pradesh, Maharashtra, Madhya Pradesh, Karnataka, and Gujarat have grown Mahyco-Monsanto Bt cotton during Kharif 2002, 2003 and 2004. Full studies containing detailed data on various claims and doubts are yet to come out in the open. In April 2003, the GEAC denied the commercial clearance to Monsanto's Bt cotton for the north Indian states. In May 2004, GEAC has granted permission to Rasi Seeds to sell Bt cottonseeds in central and south India.

Performance of Bt Cotton in India: Recent Experiences

The legal introduction of GM crops in India began with genetically modified cotton that are resistant to bollworm attack and was introduced by the Maharashtra Hybrid Seed Company (Mahyco), which has a 50:50 partnership with Monsanto.[2] So far, cotton remains as the single GM crop that has been allowed for sale in India.[3] The company's claim with respect to the GM variety is that: (a) Bt Cotton will reduce pesticides use considerably; (b) cultivation costs will come down drastically; and (c) profits for farmers will increase.

Mixed reports are available on the performance of Bt cotton from different places. Qaim's study (2001) using the field trial data of Mahyco-Monsanto clearly brings out the cost advantages of Bt cotton cultivation particularly in pesticide reduction over hybrids and the conventional cotton variety. However, studies conducted by independent research agencies and the non-governmental organisations show a different trend, which is presented, in the following paragraph. The AC Neilson ORG_MARG study conducted in 2003 in Maharashtra, Madhya Pradesh, Gujarat, Andhra Pradesh, Karnataka among the bollgard cultivators (1672 farmers) and the conventional cotton cultivators (1391 farmers) reports that the bollgard growers experienced better yield, reduction in pesticide use and a net gain which is provided in Table 4.

Table 4: Performance of Bt Cotton in Selected States

State	Reduction in		Yield		Increase in	
Bollworm pesticide	Increase		net profit			
	%	Rs.	%	Quintal per acre	%	Rs. Per acre
Andhra Pradesh	58	1856	24	1.98	92	5138
Karnataka	51	1184	31	1.36	120	2514
Maharashtra	71	1047	26	1.48	66	2388
Gujarat	70	1392	18	1.20	164	3460
MP	52	889	40	2.2	68	3876
All India Weighted average	60	1294	29	1.72	78	3126

Source: AC Neilson survey 2004.

As evident from this table the performance of Bt cotton in these states has been better as compared to the conventional variety. However, the study conducted by the Andhra Pradesh Coalition in Defence for Diversity (APCIDD) showed a different result. According to APCIDD study, in Kharif 2002 about 1200 farmers cultivated Bt cotton in Warangal district alone. Warangal district is the highest cotton-growing district as well as the highest Bt cotton grower in the state. More than 90 per cent cultivated Bt Mech 162 and the variety was a miserable failure according to the APCIDD study. The Monsanto study on the other hand showed good results and the failure was attributed to the bad monsoon and a dry year.

In the next season of Kharif 2003, APCIDD continued its season-long study and added two more districts Adilabad and Kurnool. Twenty eight villages and 164 farmers were selected and were visited every fortnightly by 11 NGO volunteers and the APCIDD technical team members. Monsanto also contracted AC Nielsen for the study. The comparative results are given in Table 5.

Table 5: Comparative Results for Andhra Pradesh

	Characteristics	Monsanto Neilsen Study	APCIDD Study
1.	Bollworm Pesticide Reduction		
	Quantity	58 per cent	14 per cent
	Cost	Rs. 1856	Rs. 321
2.	Yield Increase		
	Percentage	24	2
	Quantity	1.98 qu/ac	0.09 qu/ac
3.	Increase in Net Profit		
	Percentage	92	-9
	Monetary	5138	-750

Source: Compiled by Authors.

Working out the economics of cotton cultivation, Suman Sahai (2002) observes that the farmers in Maharashtra perceived that they need about 1 kg of seed per acre, which works out to a cost of Rs. 700 to Rs. 900 per acre depending on the variety. All available hybrid seeds cost between Rs. 300 and Rs. 450 per each 450 gms bag. For the sake of calculations, she has considered the seed cost to be an average of Rs. 800 per acre. Pesticide sprayings work out to another Rs. 1000 per acre. Wardha and almost all of Vidarbha is rainfed so the yields are lower compared to the irrigated areas in Punjab and Haryana. The average cotton yields are around 3 quintals per acre in this region. In this situation, two new varieties of cotton, one legal and the other illegal have become available to farmers. The Mahyco-Monsanto varieties are priced at Rs. 1600 per bag. The economics in this case will be: cst of seed per acre will go up to Rs 3200. If pesticide use is reduced because of the Bt toxin, say even by as much as a dramatic 60 per cent, savings on pesticide will work out to Rs. 600 per acre. The yield will not be affected much since Bt cotton has not been bred to confer a yield advantage but has the advantage of disease resistance. Also the lack of irrigation facilities will work against the yield increase. Therefore, the economics of Mahyco-Monsanto's Bt cotton look very unfavourable for the farmer. A total outlay of Rs 3600 (3200 for seed + 400 for pesticide) as against Rs 1800 per acre in the old system (800 for seed + 1000 for pesticide) is worked out. This means an increased outlay of Rs 1800, which is double. The cost advantage in case of Bt thus appears doubtful according to her study.

Gupta and Chandak's study (2004) was conducted in various parts of Gujarat except Kutchch where 363 farmers were surveyed in 2001-02, the year when Navbharat was formally selling seeds. The survey revealed that farmers who had used Mahyco seeds experienced higher yield with higher costs. Navbharat and its derivatives provided higher yields than normal hybrids at a much lesser cost.

GEAC's own study also observes that the Bt cotton did not perform well. Following widespread complaints of failure of Bt cotton in Madhya Pradesh in early last year, GEAC commissioned a seven-member team of scientists to evaluate the performance of the crop. This study reported that Bt cotton failed in Madhya Pradesh due to wilting and large scale drying of the crop at the peak bolling stage accompanied by leaf dropping and shedding as also the forced bursting of immaculate bolls. According to the study non-bt plants performed much better[4] (Krishnakumar, 2004). The panel set up by the Gujarat government also said that 'it is unfit for cultivation and should be banned in the state[5] (Krishnakumar, 2004).

Thus, while the company-sponsored studies present a positive picture, the other studies emphasize that the Bt variety neither has cost advantage nor yield advantage. While the above mentioned studies have compared the performance of Bt cotton and the conventional cotton, Jatan, a network of farmers and organizations propagating organic farming in Gujarat in collaboration with the Gujarat Institute of Development Research, Ahmedabad undertook a study of selected farmers in Gujarat who had grown Bt during the 2002-03 agricultural season. The objectives of the study were to: (a) understand the impact of Bt cultivation; (b) analyse the experience of farmers cultivating approved Bt cotton; (c) understand the farmer's awareness about cultivating approved Bt cotton; (d) identify whether the conditions set forth for the cultivation of approved Bt cotton had been followed; and (e) compare the performance between approved Bt cotton and unapproved Bt cotton in the agricultural year 2002-03. In ten districts of Gujarat, 410 farmers were surveyed for the study. The chosen districts were Kutchch, Sabarkanta, Gandhinagar, Bhavnagar, Rajkot, Bharuch, Vadodara, Surendranagar, Amreli and Narmada which are all traditionally cotton growing areas. The sample is purposive and covered only those farmers cultivating Bt cotton (approved and unapproved variety) and the survey was carried out by Jatan volunteers. In subsequent paragraphs we discuss the performance of the approved and unapproved variety in Gujarat. Table 6 gives details on the sample farmers' distribution in the state.

Table 6: Distribution of Sample Farmers in Gujarat Growing Approved and Unapproved variety in 2003-04

Districts	Total farmers selected	Farmers growing Bt Cotton	Farmers growing Bt. Like and Non Bt Cotton	Percentage growing Bt Cotton
Kachchh	115	38	77	33.04
Sabarkantha	46	40	6	86.96
Bhavnagar	178	88	90	49.44
Bharuch	26	15	11	57.69
Others	45	15	30	33.33
Gujarat	410	196	214	47.80

Source: Field Study.

It should be noted that three out of four districts that find a place in the table are dry and drought prone and Bharuch is not prone to drought and has black cotton soil that is well-suited for cotton crop. Surendranagar is another district that is semi arid and has a substantial area under cotton, but the study has not been able to cover a significant size of farmers from this district. It may be noted from the table that the Sabarkantha and Bhavnagar farmers have gone in for the Bt variety of cotton a big way. Both groups of farmers have experienced frequent failures in growing hybrid cotton. Since all the farmers reported growing Bt cotton, we used the price criterion to distinguish the approved and unapproved variety cultivators. Thus, all those farmers who reported paying a price of Rs.1600 per packet of seed were classified as Bt growers and the others as unapproved Bt growers. The price of the unapproved variety ranged from Rs.50 to 1100. Generally the F2 (second generation) seeds do not have any fixed price level and are priced much lower than the F1 (first generation) varieties.

Most of the farmers in the study reported their main occupation as agriculture. In all six out of 410 cotton growers reported their main occupation as service (4), business (1) and labour (1). With regard to formal educational levels, the sample distribution was interesting. The details are contained in Table 7, which reports that relatively formally literate farmers have chosen Bt. cotton. Of all farmers, 68 per cent who reported growing Bt cotton were educated at least up to 10th standard, whereas among the unapproved cotton growers the percentage was 31. It may be said, therefore, that literate farmers are more likely to experiment with newer varieties such as GM crops as and when they are released.

Table 7: Educational Levels of Farmers among Cotton Growers

Educational Level	Percentage of farmers in approved Bt. Cotton category	Percentage of farmers in unapproved Bt. Cotton category	All farmers
Illiterate	7.14	14.48	10.97
Can read and write	35.20	54.21	45.12
Up to 10th standard	28.06	19.63	23.66
Up to 12th Standard	14.80	7.48	10.98
Graduation	11.73	3.74	7.56
Post Graduation	3.07	-	1.47
Others	-	0.46	0.24
All	100.00196	100.00214	100.00410

Source: Field survey.

How long have the farmers been cultivating cotton and Bt. cotton? In answer to this question we learnt that more than 58 per cent farmers have more than seven years experience in growing cotton. Interestingly, there are also first time growers and out of the 26 first time growers 18 or about 70 per cent chose to grow Bt cotton. Table 8 contains details on the experience of farmers in growing cotton under Bt and other than Bt category. A large chunk of farmers with more than seven years of experience in cotton cultivation have gone in for both the approved and unapproved variety of cultivation, perhaps in the hope of recovering from their loss.

Table 8: Number of Farmers by Years of Experience in Cultivating Cotton

Years of experience cultivating cotton	Approved Bt	Unapproved Bt	Totali n
First time	19(9.7)	27(12.7)	46
Less than 4 years	47(24)	28(13.1)	75
4 to 7 years	27(14.5)	19(8.9)	46
Above 7 years	103(52.5)	139(65.3)	242
Total	196	213	409

Note: Figures in parentheses are percentages to column total
Source: field survey.

Interestingly, of the 194 approved cotton cultivators 150 or 77 per cent of farmers have 5 or less than 5 acres of land. Similarly, of the 208 farmers cultivating unapproved varieties 141 farmers or 68 per cent of farmers have less than 5 acres of land. Of the three approved varieties of Bt cotton (Mech 12, Mech 162, and Mech 184), Mech 162 and Mech 184 were more popular among the farmers, where out of the 157 farmers cultivating Bt cotton, 72 and 69 farmers had chosen Mech 162 and Mech 184 respectively. Farmers have purchased both approved and unapproved Bt seeds by paying cash. Farmers have chosen cultivation of Bt to avoid pest's attack and to get a good yield. Eighty per cent of the farmers have bought seeds from the recognized seed agents. Since, the majority of the approved Bt cotton cultivators have bought the seeds from approved agents, we expect the farmers to have received appropriate information about the technology and the precautions that they should take while cultivating the new variety of the seeds.

Table 9 provides details about the information provided to the farmers about approved Bt cotton. Thirty nine per cent of the farmers have confirmed that they were informed about the requirement of cultivating non-Bt cotton variety in the Bt cotton field. Only 10 per cent of the farmers reported receiving information regarding the nature of the Bt cotton and its impact on pests. Most importantly, a negligible percentage of farmers have reported awareness regarding the fact that the approved variety has been given conditional approval for three years.

Table 9: Distribution of Farmers According to the Awareness of Information on Bt Cultivation

Type of Information Given About Bt Cotton	Type of Seed Approved Bt	 Unapproved Bt	Total
Do not cultivate in less than one acre	59(38)	2	61
20% for refuge crops	61(39)	4	65
Pesticides requirement for other pests	15(9.7)	1	16
Bt. Cotton approval for 3 years	2	-	2
None of the above	17(11)	5	22
Others	-	-	-
Total	154	12	166

Source: Field survey.

When new varieties like the transgenic seeds are available, the role of diffusion agencies like the approved seed sellers and the extension workers in the private and public sector become very essential. They will have to play an active role in educating the farmers about the salient features of the seed, the nature of planting, requirement of fertilizer, timing of pesticides, etc. Adoption of new technology will be easy only if the farmers have adequate information about the new technology. However, only 11 per cent of the farmers have received information about Bt cultivation practices from the company propaganda, while 54 per cent of the farmers have received information from friends and neighbours. The role of the government agriculture department or the media in providing information about this technology to the farmers has been nil. In spite of this, 81.3 per cent of the approved Bt cotton cultivators have stuck to the refuge schedule perhaps due to the information provided by the neighbour farmers. A negligible percentage of unapproved variety cultivators have also stuck to the refuge criteria.

Frequent visits by approved agents or extension workers help the farmers in getting appropriate advise about the new technology and also in ascertaining the actual area under Bt cultivation, stages of pest attack, amount of pesticide used, impact of pollination, etc. Further, in the case of Bt technology, the performance of the crop in the field would be useful for the company/government. We expected that since the farmers have bought their seeds from the authorized sources, the role of the extension workers would be substantial. However, as evident from Table 10, out of the 155 responses for this question, 43 per cent have confirmed visits by some supervisors. But 52 per cent have responded negatively.

Table 10: Number of Farmers Confirming visit of Supervisors

Confirming visit of supervisors	Type of Seed	
	Approved Bt	Unapproved Bt
Yes	66(43)	3
No	80(51.6)	7
Don't Know	9	-
Total	155	10

Source: Field survey.

It is very interesting to observe that in terms of yield, the unapproved variety has done better than the approved variety. Specifically, farmers have obtained 4.8 quintals and 5.32 quintals per acre from the approved and unapproved variety, respectively. Table 11 reports the average yield obtained by the approved and unapproved Bt cultivators by different size of landholders. The overall outlook suggests that the yield from approved Bt cotton at 522.04 Kgs per unit of acre is higher than the 506.25 Kg per unit of acre yield from unapproved Bt cotton. Interestingly, whereas the yield from smaller size classes of approved Bt is higher than the unapproved Bt, in land holding exceeding 5 acres, unapproved Bt has yielded 451.02 kgs compared to 353.34 kgs of approved Bt.

The entire purpose of introducing Bt cotton is to save the crop from the bollworm pest attack. In India, though cotton cultivation accounts for only 5 per cent of the land, it nevertheless accounts for 50 per cent of pesticide consumption. Hence, it is of interest to see, whether there is difference in the use of pesticides between approved Bt and unapproved Bt and thereby the difference in the expenditures. Interestingly, while the approved Bt cultivators with lower size groups of land have incurred higher pesticide expenditure, the unapproved Bt cultivators have spent comparatively less. To elaborate, whereas

Table 11: Average Yield and Pesticide Expenditure

Size of land acre	Average yield in KG in approved Bt	Average Yield in KG unapproved Bt means of yield	't' values Of difference between the approved Bt	Average pesticide exp in Rs. in Bt	Average pesticide expin Rs. in unapproved pesticide expenditure	't'values of in diference between the means of
< 1	696.07 (14)	559.28 (5)	0.814	1017.14	885.44	0.281
1.1-3	717.83 (42)	695.27 (39)	0.161	859.96	686.08	0.952
3.01-5	643.57 (40)	487.59 (62)	1.73**	712.84	458.05	1.84**
5+	353.34 (92)	451.02 (99)	-1.814**	294.04	429.91	-1.999*
Total	522.04 (188)	506.25 (207)	0.335	563.42	493.45	1.049

Source: Field Survey

Note: * and ** denote significance at 10 per cent and 5 per cent level respectively. Figures in parentheses are the number of farmers.

unapproved Bt cultivators have incurred Rs.493.45 per unit of acre on pesticides in order to get 506.25 kgs of yield, the approved Bt cultivators have spent Rs. 563.43 per unit of acre on pesticides and have obtained a yield of 522.04 kgs. It should be noted that while the difference in the pesticide expenditure incurred by approved Bt cultivators is higher than that of the unapproved Bt cultivators, in the land classes exceeding 5 acres, unapproved Bt cultivators have spent Rs. 429.91 on pesticides, while the approved Bt cultivators have spent only Rs. 294.04.

Interestingly, in land size classes less than 3 acres, the difference in yield and pesticide expenditure is not statistically significant But in the size class of 3 to 5 acres, the difference between yield and pesticide expenditure between the approved and unapproved variety is statistically significant indicating that though approved Bt has better yield performance, the pesticide expenditure is also high. In the higher land holdings, yield performance of unapproved cotton is higher than the approved cotton variety and it is statistically significant. Also, the difference in the pesticide expenditure of the approved and unapproved variety is negative and significant which implies that in order to get a higher yield, farmers with large size classes of land incur more expenditure on pesticides. But overall, there is no significant difference between the approved and unapproved varieties either in terms of yield or in terms of pesticide expenditure.

While only 9 per cent of the farmers cultivating Bt have not used any pesticides, this percentage is smaller (6 per cent) for the non-Bt cultivating farmers. Pesticides use up to 3-4 times appear to be a common norm for both approved Bt (40 per cent) and unapproved Bt cultivators (48 per cent) (see Table 12).

It was also observed that 27 and 18 per cent of the approved and unapproved cultivators have been using the residual of cotton as cattle feed and thus the Bt cotton has entered the human chain. Farmers have not observed any adverse impact on health. The limited information that we have provided here shows that there is indeed a difference in the yield performance of the unapproved variety compared to the approved variety. This coupled with the fact that the price of the unapproved variety is relatively lesser than the approved Bt has prompted the farmers to adopt th e unapproved variety.

Table 12: Use of Pesticides by Approved Bt and Unapproved Bt Cultivators

Pesticides Use	Approved	Unapproved	Total
Not even once	18 (9%)	13 (6%)	31
1-2 time	49	45	94
3-4 time	78 (40%)	102 (48%)	180
5-6 time	24	28	52
7-8 time	15	17	32
9-10 time	10	3	13
11-15 time	2	2	4
>15 time	0	2	2
Total	196	212	408

Source: Field survey.

Implications and Issues in Bt cultivation

Presently, there are two kinds of problems facing the government. One pertains to the uncertain and the mixed performance reports on Bt cotton while the second and more serious is the spread of the unapproved variety in various parts of the country, which cannot be withdrawn. In fact, this is one of the problems with GMOs that once they are released in the open, it is very difficult to recall or rectify the damage.

It is true that the promise of less pesticide expenditure and thereby better yield has attracted a number of farmers to Bt cultivation and particularly more towards the unapproved variety in Gujarat which according to the farmers is better suited to the Gujarat soil. A survey done by GIDR showed that the Mech 12 variety did not yield at all and between Mech 184 and 162 Mech 162, performed better. But the realization came only after farmers tried the variety in their field. This survey also highlighted that certain traditional varieties such as Gujarat 23, Gettu or the Digvijay variety released by the State Seed Corporation have not been affected by the pests at all and these farmers have not incurred any expenditure on pesticides. It suggests that only the hybrids and the high yielding varieties have been prone to pest's attack. Similarly, the Vagad Kapas and Varahlakshmi varieties that were popular in the dry regions of Saurashtra and Kachchh, had lesser pest problems and low but assured yields. The emphasis shifted from drought and pest resistant varieties that had become well acclimatized over decades and centuries to hybrid varieties that yielded better but had a high fluctuation rate. High mean-high variation became the name of the game and low mean-low variation lost out. The Bt game is about the same high mean –high variation trend.

The spray of Bt or Bacillus thuringiensis, a common soil bacterium, is one of the most important biological pest control techniques in use worldwide. The genetic engineers have done a marvelous thing by developing transgenic crops containing the insecticide gene of Bt, so that the plant itself makes the protein necessary for protection against pests. This is being adjudged as the single biggest commercial application of r-DNA technology in the world so far. However, it makes a lot of difference when Bt is used as a spray and the plant itself acts as a pesticide. In fact, there is a growing concern that the very effectiveness of Bt as a bio-pesticide could be irrevocably endangered if the use of Bt-transgenic plant varieties is not stopped immediately. Rigorous field studies of teams led by Bruce Tabashnik (University of Arizona) and Fred Gould (North Carolina State University), both reported in recent years in the Proceedings of the National Academy of Sciences, US, evidence of insect resistance to Bt cotton.[6]

Interestingly, the North Carolina State University's research study reported that 1 in 350 tobacco budworms carried resistance to the Bt toxin. This estimate forewarns: (a) of a swift evolution of resistant insect populations, and (b) that with 4 per cent refuge, the Bt cotton could remain effective against tobacco budworm for 10 years. However, Bt cotton has less resistance to other pests such as cotton bollworm and European corn borer and hence this study predicts a boom cycle of only 3-4 years for Bt.[7] Bt cotton is not effective against other pests like boll weevil and whitefly.

A recent study[8] by a scientist from Indian Agricultural Research Institute found that the bollworm developed resistance to the toxin CRY 1AC within six generations. Earlier the Central Institute for Cotton Research in Nagpur also showed that the bollworm could develop resistance within 10 generations. According to scientists this article states that there are two strategies to counter this resistance. One is the expensive strategy to introduce a dual gene system where if one toxin fails the other one would act. The second consist in planting adequate amounts of refuge where the resistant insects breed with the counterparts surviving on the non-Bt crops so that the resistant trait gets diluted in the next generations. However, the GIDR survey shows that increasingly farmers are ignoring the refuge, though the Mahyco seed packet does contain a 150 gram packet of non Bt seeds. The reason for ignoring this is that this non-bt attracts a lot of bollworm and the farmers do not want to risk their Bt crop by exposing them to these bollworms. This only explains that the farmers have not been adequately informed either by the company or by the government officials about the role of the refuge in the cultivation of Bt cotton. Critics such as Suman Sahai have argued that in a country like India where the holdings are small and hardly enough to feed the family on the land that is operated, farmers will have hardly any incentive to provide 20 per cent of the acreage for non Bt cotton. Keeping the issue of scientific validity of ensuring 20 per cent refuge a side for a while, a question that begs the answer is: has Mahyco-Monsanto strictly monitored the refuge plantation? The company-sponsored studies are silent on this aspect.

These resistance arguments pose the specter of a scenario in which that Bt seeds become useless. Can farmers in this case go back to their original seeds? If yes, what will be the intensity of the bollworm attack? Would the situation be worse than that of a cultivation scenario without Bt gene or would it be the same?

The other concern is the spread of the unapproved variety in several parts of the country. This should be fully attributed to the lack of monitoring and regulation, which has resulted in farmers indiscriminately crossing any variety of cottonseed. The impact of such crossing is likely to create disasters in the future. This is because, farmers are developing Bt cotton hybrids in their own fields without adopting any standard protocols that are needed in producing seeds like separation of the field to check for pollination from other variety and so on. Basically farmers cross the male line of unapproved Bt gene with the locally acceptable female line. Such crossings may result in a progeny, which has just one copy of the Bt gene or none depending on the number of copies of the Bt gene in the unapproved Bt. In subsequent generations the number of seeds having the Bt gene would decrease. This will result in the growing of Bt and non-Bt crops together. This would lead to the insects developing resistance to the toxin much faster than would happen with exposure to the ones containing Bt genes alone. This is because there is a possibility of the insects that have fed on the Bt crops to jump over to the neighbouring non-Bt crop and thus survive from the toxic effects of the gene and slowly develop immunity to the Bt gene. Bt gene expression could be different in different cultivars it is inserted in, which means that the quantity of toxins produced could also differ. The implications of such indiscriminate crossing of the varieties are faster resistance to pests that will shorten the period that the farmers could exploit this gene. There is also the possibility of the bollworm being more tolerant to the pesticides being sprayed than before because of the new characteristics that it has acquired in the process of developing immunity towards the Bt toxin. Further, there is also the possibility of the gene transferring into other sexually compatible plants and wild relatives and because of the selective advantage of the gene, the ones without this gene may become extinct and affect the genetic resources available.

Concluding Remarks

Following the Bt cotton debate in India, it becomes clear that all is not well with the Bt cotton case in the country. Bt or GM crops are not like the seed transfers that took place in distant past when some travelers brought experimental seeds and planted them in native soils and if it took root it did; if it failed, it was forgotten. Science has tried to intervene in this process first by creating an artificial environment for the foreign crops and then it eventually tried to alter genes so that the plants are born with some characteristics that help increase the material welfare of the human being. However, scientists have been tentative as they have always been and therefore have always prescribed some dos and don'ts for the science and technological wonders they introduce and try to propagate. In the case of GM crops too it appears that the seeds cannot be simply brought and sown in the fields. They have to be tested for their scientific claims including health and yield assurance, for cost and for their negative fallouts on human health and the general environment. Some of the ill effects may be devastating.

Obviously, as we have noted in the chronology of events in introducing Bt cotton in India the players to introduce the game namely, the government and the seed company know the rules and have tried to play within the rules. Since the onus of taking the technology to farmers is on the government, its role has to be examined more critically. Government has to play two roles; one is to ensure the feasibility, viability and safety of the technology, and two, to protect farmers and breeders rights. In the second section, we have discussed the arrangements that the Government of India has made to facilitate the introduction of the GM technology. The details are about on the institutional arrangements. The issue is, do the arrangements work as they are mandated? The answer unfortunately is the negative.

In the case of Bt cotton the final regulating authority, the GEAC granted its approval to Mahycô-Monsanto to sell Bt seeds to farmers in selected states. The GEAC while approving laid down the following conditions:

1. Bt cotton will be grown with an insect refuge of 20 per cent non-Bt cotton.
2. Mahyco-Monsanto company which has developed the varieties, will 'monitor annually the susceptibility of bollworms to Bt gene vis-à-vis baseline susceptibility data and submit data relating to resistance development, if any, to GEAC'.
3. GEAC has also appointed the company 'to undertake studies on possible impacts on non-target insects and crops, and report back to GEAC annually'.

The environmentalists who form the major group of critics have come down heavily on the way in which the regulation has been implemented particularly, in entrusting the job of monitoring to the company itself. Critics have argued that the agency, which has a business and profit motive, would have a natural inclination to either ignore monitoring and would feed wrong and/or manipulated reports. According to them it was perhaps the first instance in which a company that was producing and selling the GM seed was entrusted with monitoring.[9] In the same vein there is also a related question. Four years of Bt cotton cultivation have passed. Has the company provided any feedback data to the GEAC? If so, has this been discussed in public? The following specific questions are relevant in the context of the debate.

1. How many farmers as per the Mahyco-Monsanto records followed the refuge criteria?

2. Where and what type of testing arrangements have been made to examine field level susceptibility of bollworm against the baseline data?
3. What tests have been set up and what are the findings (preliminary, intermediary or final) that have been documented and reported by the company with regard to impact on non-target insects and crops?
4. What is GEAC's assessment about the two year's experience of growing Bt cotton in the country and what are the basis or grounds on which the clearance to northern states have been withheld?

The government needs to answer at least some vital questions with respect to the process of approval followed. We have noted that the Government granted approvals to the company to undertake small and big trials on farmers' fields. However, at the time of the approval, the government did not accept the results of the company's trials that went on for a few years and later accepted the trials that were done for a year under the supervision of ICAR. The results of the trials and the report of the ICAR have not been made public for the purpose of an open debate about the technology and its impact. Since the decision is likely to impact thousands of farmers in the country, the results of trials pertaining to feasibility, viability and possible environmental effects should be made public. Transparency is vital in introducing technologies where uncertainty looms large. Going back to the process of granting clearance, the government should also make public its decision to burn the Bt - like cotton standing on the field in October 2001. Was it because it was dangerous and likely to cause serious irreversible environmental damages? And when it faced a lot of resistance from the farmers and the fields could not be burnt what corrective measures were taken? What stand has government taken on the court case challenging the Navbharat Seeds' move to introduce cotton seed containing GM material without permission vis-à-vis the Mahyco-Monsanto claims? What would be the responsibility of the company wherever the crop has failed?

Now let us turn our attention to the most important argument of the whole debate and that is the economic viability from the farmers' viewpoint. Unfortunately, the evidence is thin on both the sides. The proponents of the technology have also not come with detailed sample studies of farmers who have cultivated Bt cotton for two seasons now. Ideally, there should have been some cohort studies launched by the Company that is interested in selling more seeds, or by the agricultural universities in all the states or at the initiative of the ICAR as an all-India coordinated research project. Of course, NGOs and 'concerned scientists' should also have undertaken such a study of farmers' cohorts. There have been some cross-sectional studies in some states.

Bt is not for yield advantage. Higher yields are linked to irrigation. Hence, the comparative advantage has to be analysed based on the cost and investment and not with the output side. Profitability increase is due to decreased cost by means of savings in pesticides sprays that have become very expensive. The claim is that spray technology has become expensive and is relatively ineffective while seed technology is more effective. The industry's claims regarding the reduction in cost and increased profitability of Bt cotton growing enterprise appears to raise serious questions. As pointed out earlier, it is necessary to undertake a longitudinal study of selected farmers for controlling physical factors, land holding and the educational levels of farmers. The thin and scattered evidence that one comes across is inconclusive.

Now let us turn our attention to the third aspect that relates to environmental/ecological impact of GM crops with particular reference to the experience of Bt cotton in India. We have noted that the international scientific community has raised concern to do with the resistance issue. We are perhaps yet to record any resistance or will the resistance build up late? How late? What will the farmers do then? If the successful generations of seed lose potency in some way even of the pest toxin, the farmer's dependence for seeds will become total on one or two seed companies. The companies and the scientists promoting this in the private sector and regulating it can be negligent, collusive and profits oriented and mass keep playing this game till it pays. So in case of failures where do the poor farmers to in that case? Do they have clear rights to claim compensations?

Spread of the unapproved variety in different parts of India is a mockery of the regulatory mechanism. It also signals that farmers are willing to take risks for short-term gains. The Government of India is not averse to the technology as evident from the field trials that are going on in the public and private sector. In such a situation it is only necessary that the government in the interests of the farmers should provide adequate information about the positive and negative impact of the technology. Unchecked spread of the unapproved variety will lead to companies bringing in terminator genes or some other technology to protect their interests which will nullify the rights of the farmers to 'save, use and sell' the seeds of the protected varieties in future. This also forewarns that technological breakthroughs in this field will not be diffused adequately to benefit the farmers in developing countries, if adequate intellectual property protection is not provided.

Even when all these issues remain unanswered, the government has approved another transgenic Bt cotton RCH 2 for commercial cultivation in the central and southern parts of the country. Our field observations suggest that farmers are not fully informed about the technology either by the company or by the government. It is not clear whether the company should be held responsible for not providing adequate information or whether the government should in the overall interest of the farmers and society contribute to their awareness through extension workers even though the technology is diffused by the private sector. Further, the elaborate institutional framework to regulate and monitor this technology should function efficiently which requires capacity building and the information from the bottom should reach the top. The questions and issues that we have raised in this paper should be considered when the conditional approval is reviewed in 2005 by the regulatory agencies. In the absence of this, an important breakthrough in science would loose its advantage in the maddening rush to make quick gains.

Endnotes

[1] Srinivasan (2004).

[2] A short account of the approval process for the commercialization of the Bt cotton in India is detailed in Iyengar and Lalitha, 2002.

[3] Commercialization of Bt mustard has been stalled due to the absence of information on the economic viability of the crop to the farmers.

[4] *Fronline,* May 21, 2004.

[5] *ibid.*

[6] Shiva and Jafri (2003).

[7] Prakash (1997)

[8] This paragraph draws upon the article published in Frontline, May 21, 2004.

[9] Again the field observations from the GIDR survey confirm that neither the company nor any government officials contacted the farmers regarding the performance of Bt cotton or for any impact of the seeds.

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Plant Biosecurity in India - Status and Strategy

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Abstract: Plant biosecurity encompasses the policy and regulatory framework to analyse and manage risks in the sectors of plant life and health, and related environmental concerns. It covers the protection of a country from pests during transboundary movement of commodities, from emerging indigenous pests/ diseases, from introduction and release of GMOs (genetically modified organisms) as well as from the use of pests/ diseases/ GMOs in biological warfare. The plant quarantine legislation in India is aimed to protect the country from an ingress of exotic pests during import. The Department of Biotechnology under the Ministry of Science and Technology, through its various committees, takes care of the biosafety issues in dealing with GMOs and the issue of biological warfare is presently dealt by the Ministry of Home Affairs. Critical issues that need to be addressed include upgradation of quarantine facilities, strengthening the risk analysis mechanism, development of the pest database, standard operation procedures and research prioritization. There is an urgent need to work on exotic and emerging diseases with a focus on developing early warning systems and risk analysis models. The need for developing a National Biosecurity Policy and a strategy for effective convergence of related activities of all stakeholder departments and ministries is self evident in the present global scenario.

Keywords: Biosecurity, biosafety, biological warfare, plant quarantine, trade.

Introduction

Biosecurity is a strategic and integrated approach that encompasses the policy and regulatory framework to analyse and manage risks in the sectors of food safety, animal life and health, and plant life and health, including associated environmental risk. It covers the following:

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- The introduction of plant pests, animal pests and diseases, and zoonoses.
- The introduction and management of invasive alien species and genotypes.
- The introduction and release of genetically modified organisms (GMOs) and their products. (http://www.fao.org)

Thus, biosecurity is a holistic concept of direct relevance to the sustainability of agriculture, food safety, and the protection of the environment, including biodiversity. It encompasses the concept of biosafety which is the term used to describe policies and procedures adopted to ensure the environmentally safe application of modern biotechnology. The recent advancements in biotechnological products derived from the use of recombinant DNA technology has led to global concern on biosafety issues. This article deals mainly with the phytosanitary aspects of biosecurity with a focus on dangers from exotic pests, including those which are invasive, the status of preparedness and the need for a holistic approach to address the issues.

Need for Biosecurity in Trade and Exchange Programmes

The introduction of pests into a new locality is brought about in various ways namely: (a) the host may be the carrier; (b) inert materials such as packing material may carry resting stages of the organism; (c) insect vectors and birds may transport it; (d) air currents may carry the pest over long distances; or (e) there may be deliberate, illegal introductions to use them as bioweapons. The first two modes of distribution lend themselves to curtailment by quarantine measures. The next two are by and large beyond human control and are a major limitation in the control of pest by exclusion. A different degree of alertness and preparedness is required for the last category.

The global trade in agricultural commodities and transboundary movement of genetic resources of plants and animals has led to situations in the past which warranted legislative measures to regulate such trade/ exchange. Plant quarantine is the government endeavour enforced through legislative measures to regulate the introduction of planting materials, plant products, soil, living organisms, etc. in order to prevent inadvertent introduction of pests (including fungi, bacteria, viruses, nematodes, insects and weeds) harmful to the agriculture of a country/ state/ region, and if introduced, prevent their establishment and further spread.

The devastating effects resulting from diseases and pests introduced along with international movement of planting material, agricultural produce and products are well documented.[1] The historical Irish famine of 1845, caused by late blight of potato introduced from Central America; coffee rust introduced in Sri Lanka in 1875 and its subsequent introduction in India in 1876; fluted scale on citrus introduced from Sri Lanka in 1928; San Jose scale in apple introduced into India in 1930s; bunchy top of banana introduced from Sri Lanka in 1943; the dreaded Golden nematode infesting potatoes introduced in 1960s from the UK and the noxious weed *Lantana camara* introduced in 1809 from Central America are glaring examples that clearly demonstrate that introduction and establishment of quarantine pests including weeds into new areas can severely damage the crop production and economy of a region/country.

Infectious diseases in poultry and livestock cause an annual loss of about Rs 50 billion, besides the losses due to export restrictions and the impending danger of public health hazards. In the case of epidemic outbreaks the losses are much more colossal.[2] Notable examples include Swine fever in 1962 causing a mortality of 3500 pigs, African horse sickness in 1960 which resulted in the death of over 22,000 equines between 1960- 63 and the introduction of hydro-pericardium (Lichi disease) of poultry through cross-border transmission. The recent case of H5N1 avian influenza virus first reported from Vietnam and China in December, 2003 has since killed 166 people and has been reported from 11 countries, namely Azerbaijan, China, Cambodia, Djibouti, Egypt, Iraq, Nigeria, Indonesia, Thailand, Turkey and Vietnam.[3]

Instances of crop pests being used or the credible threat of use for agro-warfare include: the dropping of the dreaded Colorado potato beetles (*Leptinotarsa decimlineata*) by Germany in the potato fields of the UK during World War II; Cuba accused US of attacking Cuban crops on several occasions through pests like tobacco blue mold, sugarcane rust and *Thrips palmi;* the threat by opponents of the Idi Amin regime to poison Uganda's coffee and tea plantations to deny the government foreign exchange, and recently, a Florida University professor informed the CIA that an outbreak of citrus canker in Florida was a result of the Cuban biological weapons programme.[4] Moreover, the trend towards planting monocultures that have a high degree of genetic homogeneity, the concentration of a single crop in one region and the intensive rearing of animals all aid the disease spread. As recently revealed by the US, Iraq had a wheat smut bomb and stockpiles of wheat rust spores while aflatoxin and anthrax spores were also used in powdered forms during the US-Afganistan war. *Clostridium tetani, Clostridium botilinum, Salmonella typhimurium* organisms are being used as weapons in agro-warfare, in case of which cases the targets are vulnerable and the security low.

After the Second World War, FAO convened an International Plant Protection Convention (IPPC) in 1951, to which India became a party in 1956 along with Australia, Sri Lanka, UK, the Netherlands, Indonesia, Portugal and Vietnam. At present, there are more than 160 signatory members of the IPPC. The IPPC aims to develop international cooperation among various countries to prevent the introduction and spread of regulated pests that may accompany international movement of plants and planting material (http://www.ippc.org). The IPPC requires that each country establish a national plant protection organization to discharge the functions specified by it.

Risk Associated with Imports

Based on the quantity, plant/ planting material are either imported as bulk material for sowing/ planting or for consumption while small samples of trial and germplasm are required for research work. Of these, bulk imports for sowing/ planting carry maximum risk as thorough examination and treatment becomes difficult and the planting area required is also too large. Quarantine processing is often restricted to smaller samples derived from them and based on the results of these samples the whole consignment is rejected/ detained or released after giving fumigation treatment or fungicidal/ insecticidal treatments. The bulk consignments meant for consumption pose lesser hazards. However, certain small samples meant for research purposes are of immense quarantine importance. These samples usually comprise of germplasm material or wild relatives or landraces of a crop, and are thus more likely to carry diverse biotypes/ races/ strains of the pest. Besides, in case of true seed, generally, risks are more due to deep-seated infections than with surface-borne contamination. However, the import of vegetative propagules present a much higher order of risk than true seeds.

In case of import of animals too, there is always a risk of the introduction of new diseases/ pathogenic organisms into the country causing serious animal health problems. Once such pathogens are introduced into a country, they can cause epidemics due to the absence of diagnostics, vaccine or effective drugs, lack of resistance in the host animals. Hence, there is a need to take extra precaution in the import of livestock and livestock productions infected with such pathogens.

While discussing biosecurity, a threat from the exotic destructive pests is of foremost importance in this era of liberalized import under the WTO. However, with the changing conditions, the indigenous pests already existing but having lower damage levels in India are changing their habit and gaining more importance over the years. There are new diseases emerging at an unprecedented rate over the last decade without any clear-cut explanation of the reasons for their emergence or recurrence. These diseases now continue to spread over large areas. These include foliar blight in wheat, necrosis in sunflower, bract mosaic in banana, sheath blight in maize and paddy, pyrilla in sugarcane, etc. and the number of such pests/ diseases continues to grow while inflicting increased crop losses. Likewise in the livestock and poultry sector also various diseases have emerged and were responsible for heavy economic losses. These include *peste des petitis ruminants* (PPR), Blue Tongue, Babesiosis, Cysticercosis, Anaplasmosis, infectious bovine rhinotracheitis/ infectious pustular vulvo-vaginitis (IBR/IPV), Theileriosis, Contagious agalactiae (Mycoplasmosis), Enzootic abortion (ovine chlamydiosis), Caprine arthritis/ encephalitis (CAE), Maedi-visna, Contagious caprine pluropneumonia (CCPP), Equine influenza, Equine piroplasmosis, Equine viral rhino-pneumonitis, Bovine viral diarrhoea (BVD), Bovine immunodeficiency virus infection (BIV), Infectious hydropericardium (Hydropericardium syndrome), Bovine leucosis, etc.

With the change in cropping system there is a resurgence of pest problems such as necrosis in sunflower and groundnut, leaf curl in potato, etc. which are warning signals that cannot be neglected in the attempt to sustain the crop production and food security. Also, with the excessive use of chemical pesticides, a number of resistant strains of pests have evolved which constantly need improved mitigative measures. Apart from the threat posed by resurgence, a large number of diseases are endemic in nature and continue to cause losses in a given area, e.g. Karnal bunt in wheat, brown plant hopper in paddy, yellow mosaics in pulses, etc. in agriculture while in livestock and poultry these include: Foot and mouth disease (FMD), anthrax, clostridiosis, leptospirosis, etc. There is a need to understand the genetics of resistance to major diseases, identify the genes for resistance/ durability of resistance in important crops like rice, maize and grain legumes, by pyramiding both conventional and molecular genes for resistance. Efforts also need to be made to unfold the etiology of certain diseases that remain of unknown etiology and to develop diagnostic protocols for seed certification for use by the certification agencies or seed testing laboratories as they are immensely important in trade.[5]

Threat of Biowarfare

The potential for dangerous pests not reported from India being misused or mishandled and thereby threatening the ecosystems on a large scale is also an issue of national concern. The agricultural economy is vulnerable to threat from exotic pests/ diseases that have the potential to be used as bioweapons (see Table 1). Besides, a large number of destructive agricultural pests have strains/ isolates/ biotypes reported which also have a potential for use as bioweapons. These include viruses such as *Rice tungro bacilliform virus* with four variables isolated from South Asia; *Rice tungro spherical virus* whose Indian isolate is different from the South-East Asian isolates, *Cotton leaf curl virus* which causes severe damage in Pakistan but has a limited distribution in India, *Groundnut bud necrosis virus* having a wide host range, *Banana bunchy top virus* with five identified strains and *Tobacco streak virus, Citrus tristeza virus* and *Mungbean yellow mosaic virus* with several strains reported. The pathogens causing serious diseases where variability has been reported are cereal rusts caused by *Puccinia triticina* (whose spores are air-borne of which a number of virulent pathotypes are known), rice blast *(Pyricularia oryzae,* where a high degree of variability has been reported), *Bulkholderia solanacearum* (race 2 of which is not known in India) and *Xanthomonas campestris* pv *malvacearum* (of which the most virulent pathovar in Africa - XcmN is not known in India). The insects where biotypes have been reported include *Bemisia tabaci,* (a highly polyphagous pest which attacks >600 host plant species has 16 known biotypes); brown plant hopper *(Nilaparvata lugens,* where biotypes from India differ from those in other Asian countries); rice gall midge *(Orseolia oryzae,* has six biotypes known from India), red flour beetle *(Tribolium castaneum,* whose strains show variability in level of pesticide resistance). Several races are also reported for nematodes like *Meloidogyne incognita, M. javanica/ M. arenaria* and *Heterodera avenae.*

Table 1: Major Threats from Devastating Exotic Plant Pests/ Diseases

Bacterial and Fungal Pathogens

- Bacterial wilt and ring rot of potato (*Clavibacter michiganensis* sub sp. *sepedonicus*)
- Fire blight of apple and pear (*Erwinia amylovora*)
- Black pod of cocoa (*Phytophthora megakarya*)
- Powdery rust of coffee (*Hemileia coffeicola*)
- Sudden death of oak (*Phytophthora ramorum*)
- South American leaf blight of rubber (*Microcyclus ulei*)
- Vascular wilt of oil palm (*Fusarium oxysporum* f sp. *elaedis*)
- Soybean downy mildew (*Peronospora manshurica*)
- Blue mold of tobacco (*P. hyocyami* sub sp. *tabacina*)
- Tropical rust of maize (*Physopella zeae*)

Virus, Viroid and Phytoplasma

- Barley stripe mosaic virus
- Coconut cadang cadang (Viroid)
- Palm lethal yellowing (Phytoplasma)

Nematodes

- Pine wood nematode (*Bursaphelenchus xylophilus*)
- Red ring nematode of coconut (*Rhadinaphelenchus cocophilus*)

Insects

- Mediterranean fruit fly (*Ceratitis capitata*)
- Cotton boll weevil (*Anthonomus grandis*)
- Russian wheat aphid (*Diuraphis noxia*)

Source: Khetarpal and Gupta, 2006c.

Ethically, the potential for harm must be weighed against the scientific or commercial freedom for research and to develop microbes for useful reasons. Given the invasions of ecological systems by alien species, as well as the potential for bioterrorism, we need to foster policies and technological capabilities to prevent, detect, and respond to incidents involving such acts. Lack of genetic diversity in certain cases limits natural defenses to disease and to biological agents that are intentionally introduced into an environment.

Introduction of naturally-occurring or manmade genetically modified (e.g., recombinant DNA) viruses and experimental biotechnology into weaponry, livestock, crops and medicine is controversial because, if not adequately controlled, these may threaten the well-being of entire populations and ecosystems. The new biological strains of plant pathogens can easily cause significant harm, as often observed in the case of livestock, because they rapidly infect elements of ecosystems that have not yet developed immunities.

Ensuring Biosecurity during Trade and Exchange: National Scenario

Legislation

The Government of India legislated the Destructive Insects and Pests (DIP) Act in 1914. This Act has been amended through various notifications issued from time to time and also has provision for domestic quarantine to restrict the movement of certain planting material from one state to another state. In 1984, a notification was issued under this Act, namely Plants, Fruits and Seeds (Regulation of Import into India) Order popularly known as the PFS Order which was revised in 1989 after the announcement of the New Policy on Seed Development by the Government of India in 1988, proposing major modifications for smooth quarantine functioning. This order has now been superceded by the Plant Quarantine (Regulation for Import into India) Order 2003 as there was an urgent need to fill the gaps in the existing PFS order regarding import of germplasm/ genetically modified organisms (GMO's)/ transgenic plant material/ biocontrol agents, etc. to fulfill India's legal obligations under the international Agreements. Under this order, the need for incorporation of additional/ special declarations for freedom of import commodities from quarantine and invasive alien species (IAS), on the basis of standardized pest risk analysis (PRA), particularly for seed/ planting materials is also taken care of. The other salient features of the order include, prohibition on import of commodities with weed/ alien species contamination as per Schedule VIII; and restriction on import of packaging material of plant origin unless treated. Besides, the agricultural imports have been classified as: (a) prohibited plant species (Schedule IV); (b) restricted species where import is permitted only by authorized institutions (Schedule V); (c) restricted species permitted only with additional declarations of freedom from quarantine/ regulated pests and subject to specified treatment certifications (Schedule VI); and (d) plant material imported for consumption/ industrial processing permitted with normal Phytosanitary Certificate (Schedule VII).

So far, i.e., till February 2007, ten amendments of the Plant Quarantine (PQ) Order 2003 have been notified to the WTO, with revised requirements for crops under the Schedules V, VI and VII, of which Schedule VI and VII now include 411 and 284 crops/ commodities, respectively.

Issues related to IAS and GMOs are covered under the Environment Protection Act (EPA) 1986 but it does not state in clear terms the modality for restriction and prohibition of their potential threats to the environment.[6]

Infrastructure

The Directorate of Plant Protection Quarantine and Storage (DPPQS) of the Ministry of Agriculture is the apex body for implementation of plant quarantine regulations. It has a national network of 29 plant quarantine stations at different sites, for example: airports (10), seaports (10) and land frontiers (9). In all, two categories of materials are being imported under the PQ Order, 2003: (a) bulk consignments for consumption and sowing/ planting, and (b) samples of germplasm in small quantities for research purposes. The Plant Quarantine Stations under the DPPQS undertake quarantine processing and clearance of consignments of the first category (http://www.plantquarantineindia.org). The five major Plant Quarantine Stations have been modernized recently under an FAO-UNDP funded project.

The National Bureau of Plant Genetic Resources (NBPGR) undertakes the quarantine processing of all plant germplasm and transgenic planting material under exchange for which it has well-equipped laboratories and green house complexes and recently, a containment facility has also been established for processing transgenics.[7] The NBPGR also has a well-equipped quarantine station at Hyderabad, which mainly deals with export samples of the International Crop Research Institute for Semi-arid Tropics.[8]

Besides the abovementioned plant quarantine set-up, the regulation of import and export of livestock and livestock products, control of exotic disease and certification as per Office International des Epizooties (OIE) regulations is done through the Animal Quarantine and Certification Services (AQ&CS) under the control of the Department of Animal Husbandry & Dairying (DHAD) at New Delhi, Kolkatta, Chennai and Mumbai.

Sampling Procedures

In case of bulk consignments, a proper sampling of the lot is to be done as per the norms for ensuring an effective processing of the material. The amount/ size of the sample drawn and the sampling methodology used are very crucial to enable detection of miniscule amounts of pests in the samples drawn. The sampling methodology used varies for different commodities as given below.[9] However, for small samples of germplasm and samples for research purposes, sampling is not done and 100 per cent of the sample is examined and processed for quarantine clearance.

Seed for propagation

The International Seed Testing Association (ISTA) Rules, 1976, gives the detailed sampling procedures for sampling of the seed for propagation.

- The maximum size of seed lot for agricultural and horticultural crops is 20 metric tonnes (MTs) for seeds of the same size of wheat or larger. However, for smaller size seeds, the lot size is 10 MTs. For tree species with seeds of the size of the *Fagus* species or larger, the maximum is 5 MTs, and for seeds still smaller in size, it is 5 MTs.
- The sampling regime for seed lots in bulk depends on the lot size, which determines the number of primary samples required to be drawn. The sampling for seed lots in bags or containers of uniform

size depends on the number of containers, which determines the samples required to be drawn from each container.

- The sampling is usually carried out by the slotted tube sampler in the case of bagged cargo.
- In the case of sampling of seed in bulk from storage bins a sampler is used. Alternatively, the Nobbe Trier is used for sampling of seed from bagged cargo.
- In case of propagating plant material such as bulbs/ tubers/ cuttings/ saplings etc., at least 0.1% of the units are sampled for inspection in the case of bulk consignments. In the case of small consignments, a cent per cent inspection is carried out. ISTA rules provide for a minimum weight of submitted samples for various agricultural, horticultural and tree seeds.

Grain/ Pulses for Consumption

- The sampling procedures for bagged cargo of cereal grain/ pulse consignments in bags and in bulk is based on the quantity which determine the number of bags to be used as samples for example, when the lot size is 101 to 300 bags, the number of bags to be sampled would be 32. In the case of sampling of grains/ pulses in bulk, for instance, similarly 50 bags should be sampled in case the lot size is 301 to 1000 MT while 100 bags need to be sampled if the lot size is > 1000 MT.
- The samples are drawn at random from bags with the help of a slotted tube sampler or by the corn sampler in case of large size seed as that of maize, pea, beans, gram, etc. Sampling of the grain from the bins is carried out by a bin sampler or thermosampler. In case of milled plant products such as wheat, flour, spices powder, oilseed extracts, etc., a sampling by hand is practiced. A scoop or pelican type sampler is used for drawing the representative samples from the convoy at different intervals.
- Each of the primary samples drawn are thoroughly mixed and balanced to constitute a homogeneous composite sample. From the composite sample, a sample of one kg is drawn and submitted in sealed polyethylene covers with an appropriate label for detailed laboratory testing. A minimum of three samples are drawn per commodity for detailed laboratory testing.
- In case the consignment is imported in containers at least one sample is drawn from each container.

Apart from the above mentioned two main categories, the sampling procedure followed in case of root crops, edible bulbs (onions, etc), flower bulbs, cut flowers, potted plants, cuttings, nursery products (fruit trees, small plants of berries and grape wine, ornamental trees, perennials) fruits, vegetables, potato, stored products (grain, malt, flours, etc.), wood and wooden packing material varies with the type of pest known to be associated with the category and the size of the sample.

Detection of Pests

During quarantine processing, seeds and plant material are examined for the presence of unwanted weed seeds, plant debris, soil clods, insect and mite pests, plant parasitic nematodes and pathogens including fungi, bacteria, viruses, phytoplasmas, etc.

The external feeders and other incidental insect pests infesting the planting material are easily detected visually either by the naked eye or with the help of a magnifying glass or stereoscopic binocular microscope. The presence of nematodes is indicated during visual examination by the observation of galls or swellings on roots, tubers and rhizomes; white, yellow or brown pinhead sized round bodies adhering to roots; swollen or malformed leaf, stem or other tissues or root lesions or unusual root proliferation. Fungal infection is indicated by the presence of sclerotia, smut balls, malformed seeds and fungal fructifications on seed surface. Presence of yellow discolouration around the hilum is suggestive of bacterial infection.

Specialized tests used for detection of different groups of pests are given below:

Insects and mites

- X-ray radiography is used to detect seeds infested with phytophagous chalcidoids, bruchids and certain other insect groups that do not exhibit any external symptoms on the seed surface. Based on literature survey and past experience, a list of >340 plant genera has been drawn up (Bhalla et al., 2002), that are compulsorily subjected to X-ray radiography. On developing the X-ray plates, insects if present, are hand-picked and healthy seeds released to the indentor.

- Transparency method is used for detecting infestation in small seeds and seeds of family Graminae. The seeds are boiled in lacto-phenol solution (phenol, lactic acid, distilled water and glycerin in the ratio of 2:2:2:1, respectively) for 1-2 hours depending on the hardness of the seeds. This renders them transparent to reveal insect infestation.

Plant Parasitic Nematodes

- Soaking of seeds known/ suspected to carry seed-borne nematodes in water overnight softens the seeds which are teased/ crushed enabling the nematodes, if present, to come out in water.
- Soaking of some plant material in water and when sieved through nematological sieves (the finest sieve is of 400 mesh per linear inch) reveals nematodes that are retained on the sieve. These are recovered and examined under the compound microscope for identification.
- The staining technique is used for quick detection of nematodes in vegetative propagules where a part of the plant tissue (especially roots) is boiled in acid fuchsin lacto-phenol solution for a few minutes and de-stained in clear lacto-phenol. The nematodes, if present, retain the red stain more deeply than the plant tissue and can easily be detected under a stereo microscope.
- Examination of the accompanying soil shows the presence of viable nematodes especially ectoparasites and cysts of cyst forming nematodes.

Fungal and Bacterial Pathogens

- Examination of suspension after seed washing is used for detecting surface borne pathogens. The seeds are shaken in water and the resultant suspension is examined for spores of smuts, bunts, downy mildew, powdery mildew and some of the fungi like *Protomyces macrosporus* under the compound microscope.
- The blotter method is used for detection of many fungal and bacterial pathogens capable of producing mycelial growth and fruiting structures under the incubation. Seeds when placed on moist filter paper in plastic petriplates and incubated at 20 ± 1°C under fluorescent tubes in alternating cycles of 12 hours light/ darkness for seven days show growth of fungi and bacteria.

Seed-borne viruses

- Seeds known or suspected to carry seed-borne viruses are grown in insect proof post-entry quarantine net house/ environment-controlled screen houses. Seedlings showing viral symptoms are uprooted and burned. Produce from only healthy plants is released to the indentors.
- Infectivity test is done to assay the presence of virus by inoculating leaf extracts of seedlings showing symptoms on indicator hosts. This method reveals the symptomless or latent infections of plants not observed in grow-out tests.
- Observation of the sample from a leaf showing viral symptoms under the transmission electron microscope also reveals the size and shape of the virus particles, if present.
- For serological diagnosis of plant viruses enzyme-linked immunosorbent assay (ELISA), a relatively simple, rapid and sensitive technique is used for simultaneous testing of a large number of samples.

Salvaging Infested/ Infected/ Contaminated Material

Various methods used for salvaging are:

(a) The soil clods, plant debris, weeds, discoloured, deformed and shrivelled seeds are mechanically cleaned by hand picking. The vegetative propagules are cleaned by excising the infected portion.

(b) In hot water treatment (HWT) various temperature and time combinations are used for eliminating pathogens like fungi, bacteria and nematodes. The treatment is given in a hot water treatment tank fitted with heaters of different capacities, stirrer, thermostat and contact thermometer for controlling the water temperature.

(c) X-ray radiography is used to separate insect infested seeds (which do not have any external symptoms) from healthy ones. On developing the film exposed to X-rays, the infested seeds can be easily distinguished and are hand-picked from the seed geometry.

(d) Fumigation is one of the most effective methods used in quarantine for eliminating insects, mites and nematodes done either at atmospheric pressure or under vacuum conditions. Atmospheric fumigation is done at normal air pressure in an air tight container using an Ethylene dichloride-carbon tetrachloride (EDCT) mixture (3: 1) @ 320 mg/l at 30°C for 48 hrs. Vacuum fumigation is done in an especially designed fumigation chamber which helps in hastening the penetration of the fumigant through tightly packed material or internal infestation. The commonly-used fumigants are ethylene oxide and carbon dioxide mixture, hydrogen cyanide gas and methyl bromide.

(e) Pesticidal treatment is the most practical method to use in quarantine for effective control of surface feeding insects and mite, nematodes, etc. For a few nematodes in rooted plants, cuttings, tubers and other vegetatively propagated plant material, dipping in systemic chemicals at various concentrations has been found to be effective. Chemical seed dressing is generally given for eliminating seed-borne fungi and bacteria. Various systemic fungicides are available which are used as seed dressing or dips for vegetative propagules.

(f) For eliminating the seed-borne rust spores of safflower rust (*Puccinia carthamii*), the contaminated seeds are taken in a test tube containing ethyl alcohol (spirit) and a pinch of river sand and stirred with a mechanical stirrer for 30 seconds. The spores adhering to the seed surface get dislodged and separate out in the alcohol.

(g) Washing with concentrated sulphuric acid is used for destroying the spores of sugarbeet rust (*Uromyces betae*) adhering to sugarbeet seeds. The contaminated seeds are stirred with a glass rod in the acid for one minute. The treated seeds are immediately washed under the running tap water to remove traces of acid and are sun dried.[10]

(h) Chemically-treated seed materials are grown in isolation in post-entry quarantine isolation for one crop season for the detection of seed-borne pathogens. Healthy seeds from the uninfected plants are then released to the indentors.

(i) Besides, physical, chemical and mechanical methods, tissue culture technique is the safest for eliminating associated pests from the germplasm, wherever possible. Shoot tip culture is an efficient technique for raising pathogen free plants from infected germplasm. This method is based on the possibility of obtaining pathogen free progeny from a systematically infected plant by meristem culture. The technology is particularly helpful in eliminating viruses from valuable germplasm.

Interceptions in Imported Material

Over the years, during quarantine processing, a large number of pests have been intercepted in imported bulk consignments (http://www.plantquarantineindia.org/ docfiles/appendix-8) and in germplasm and other research material.[11] These pests intercepted include many that are not known to occur in India, have different races/ biotypes/ strains not known to occur in India; are present on a new host, are from a country from where they were never reported before or are an entirely new pest species hitherto unreported in science or are reported to be present widely in India (see Table 2). These interceptions, especially

Table 2: Examples of Different Categories of Pests Intercepted in Quarantine

Category of pest intercepted	Pest/ host/ source country
Not known to occur in India	*Peronospora manschurica*/ Soybean/ USA *Uromyces betae*/ Sugarbeet/ USA and Italy *Fusarium nivale*/ Wheat/ UK *Cowpea mottle virus*/ Cowpea/ Philippines *Tomato black ring virus*/ French bean/ CIAT (Colombia) *Heterodera schachtii*/ Sugarbeet/ Denmark *Anthonomus grandis*/ Cotton/ USA *Quadrastichodella eucalyptii*/ Eucalyptus/ Australia
Known to occur but the race/biotype/strain intercepted is not known to occur	*Helminthosporium maydis*/race T/ Sorghum/ USA *Pea seed-borne mosaic virus*/ Broadbean *Burkholderia solanacearum biovar 3*/ Groundnut/ Australia
Intercepted on a host on which it was never reported before	*Alternaria zinniae*/ Tobacoo/ Japan *Pseudomonas syringae* pv *syringae/Hibiscus cannabinus*/ Bangladesh *Aphelenchoides besseyi/ Stylosanthes hamata*/ Australia *Merobruchus columbinus/ Samanea saman*/ UK *Bruchus ervi/ Acacia brachustachva*/ Australia *Pachymerus lacerdae/ Orbygnya phalerata*/ Italy
Intercepted from a country from where it was never reported before	*Peronospora manschurica*/ Soybean/ Malaysia *Heterodera zeae/ Vetiveria zizanioides*/ Tanzania *Bruchus ervi/ Acacia brachustachva*/ Australia
A new species hitherto unreported	*Drechslera pluriseptata/ Eleusine coracana*/ Zambia *Tylenchorhynchus neoclavicaudatus* potato/ tubers/ USA *Polenchus minutus*/ Palm plants/ UK
Known to occur in India but possess a wide host range	*Collectotrichum graminicola, Drechslera turcica* and *Gloeocercospora sorghi*/ Sorghum/ Nigeria *Drechslera siccans*/ Soybean/ USA *Claviceps purpurea/Avena sativa*/ USA *Drechslera sorokiniana/Carthamus tinctorius*/ Italy, USA

Source: Khetarpal and Gupta, 2006a.

of pests and their variability not yet reported from India (Category 1 and 2) signify the importance of the quarantine in preventing the introduction of destructive exotic pests. The third and fourth category of pests are not expected in the sample as per the risk analysis which is literature based and since no records are available on the pest/ host their presence is unexpected and important from quarantine view point. The same is the case with the fifth category of pest as the pest is a new species hitherto unknown to science. The last category-pests with a wide host range are critical and could become invasive in case they find a suitable biotic and abiotic environment.

Besides, in the recent past, diseases like Bovine Viral Diarrhea (BVD), Malignant Catarrh Fever (MCF), Rabbit Hemorrhagic Disease (RHD), Avian Influenza (AI) have been diagnosed in the imported livestock and poultry at the entry point of quarantine. If not intercepted and controlled, these diseases would have played havoc with our livestock and poultry.

Major Issues in Import of Transgenics

The rules for safe use and release of GMOs have been notified under the EPA. The Department of Biotechnology (DBT) of the Ministry of Science and Technology reviews, permits, monitors the experiments utilizing GMOs and recombinant DNA products, while the MoEF implements their large-scale commercial use through its Genetic Engineering Approval Committee (GEAC). The biosafety guidelines prepared by DBT in 1990 which have subsequently been revised requires that every organization involved in work on GM plants set up its Institutional Biosafety Committee (IBSC) for interaction with the government. various committees have been formed by the DBT with well-defined objectives for implementing the biosafety guidelines. The Review Committee for Genetic Manipulation (RCGM) a national committee under the DBT reviews the ongoing R&D projects on GMOs, undertakes field visits of experimental sites and issues clearance for import/ export of GMOs for research and training. The RCGM has also constituted a Monitoring cum Evaluation Committee to monitor the limited field trials for which permission for multi-locational field-testing has been accorded. In addition, the concerned committees of each state and district are also involved in the monitoring of the experiments at their respective field sites.[12]

As per the PQ Order 2003, the NBPGR is responsible for ensuring that imported transgenic material is free from pests and terminator gene technology. More than 7000 samples of transgenic germplasm have been imported till date. Several interceptions have also been made in these imported transgenic samples including downy mildew caused by *Peronospora manschurica* in soybean from USA and *Cryptolestis ferrugenius* in paddy from Singapore, which are yet not reported from India. The interceptions, especially of pests not yet reported from India signify the role of quarantine in preventing the introduction of such exotic pests.

The National Plant Protection Organization needs to be upgraded in terms of manpower, infrastructure and capabilities to raise it to international standards as the increase in imports and the stipulation of WTO has brought about additional challenges to be faced by the plant protection personnel.[13] Strengthening should not only ensure prevention of exotic pests but would also check the interstate spread of indigenous pests and diseases of both plants and animals by effective implementation of domestic quarantine regulations/ certification services against certain important pests and diseases which have been introduced/ detected in the country in the recent years and which are likely to spread fast.

The new PQ Order is as an attempt to comply with the various provisions of the Agreement on Application of Sanitary and Phytosanitary (SPS) Measures of the WTO (of which India is a signatory member) and to promote trade and not to use plant quarantine measures as a technical barrier to trade. In order to prevent the ingress of exotic diseases and ensure an effective check against the spread of infection/ diseases in animals, the amendment of existing Livestock Importation Act needs to be undertaken as a priority. This may be modified as per the regulations of the OIE following the standards laid down for Australia and New Zealand which pay more attention to animal husbandry and safe export of livestock and livestock products.

Pest risk analysis is a procedure by which quarantine services can technically justify new regulations, phytosanitary guidelines or safeguards, operational procedures, entry status of imported articles and resource allocations.[14] The DPPQS has taken an initiative in undertaking PRA as per the WTO/ SPS requirements and norms but needs to be technically supported on the matter as far as expertise is concerned, as this would be the most ideal way of warding off exotic diseases by rejecting certain imports with prior knowledge and/ or permitting the imports with proper prophylactic treatments. DAHD through its Technical Committee on Animal Health is responsible for making the risk analysis and for preparing the health protocols required as per OIE norms for the import of livestock and livestock products. It should also recognize that risk analysis procedures should provide a basis for biosecurity and not create barriers to trade.

There is a need to reprioritize our research projects based on the critical gaps identified to meet the requirement for export and import. A few that need immediate emphasis are as follows:

- Survey and surveillance of disease/ pests of national and international importance to have endemic pest data.
- Generation of comprehensive epidemiological data on important pests so that *tolerance limits* can be defined, to develop PRA and to identify PFAs as per the WTO norms.
- Development of diagnostic protocols using molecular techniques for detection of exotic pests and their variants not easily detectable otherwise but are nevertheless of grave economic concern.
- Development of digitized keys for identification of exotic pests.
- Evaluation of the biosafety risks in import of transgenics and beneficial biocontrol agents.
- Development of methods to detect the presence of transgenic/ GM contamination (deliberate or inadvertent mixing of GM seed with non-GM seed) in unknown samples during quarantine processing.

There is also a dire need to develop an accessible platform for getting information on biosecurity for the policy makers, administrators and the industry groups. A website http://www.plantquarantineindia.org consisting of a national database on legislation, quarantine procedures, methodologies, etc. designed by DPPQS is available. Compilations on potential quarantine pests of various crop groups are being taken up at the NBPGR.[15] However, an internet-based portal mechanism for exchange of official information on food safety, and animal and plant health and the environment (like the International Portal for Food Safety and Animal and Plant Health), to facilitate communication among countries in these sectors needs to be developed for easy accessibility of information.

To address the issue of emerging pests in a proper perspective recently, there was an endeavour by the government to establish a National Institute for Emerging and Exotic Plant Pests with a focused mandate for the development of an early warning system for pest outbreaks, and models for pest/ disease forecasting and risk analysis; development of novel diagnostic approaches for detecting pests, imparting multiple resistance to enhance the durability of resistance by pyramiding genes or developing management strategies by developing transgenics resistant to diseases. This institute could possibly work in a network mode to facilitate research by those laboratories that are not well equipped and may boost research in the case of many regional and chronic plant diseases.

Finally, awareness about biosecurity among the scientific fraternity and general public is required to generate respect for the regulations in the interest of national security.

Developing a Comprehensive Strategy

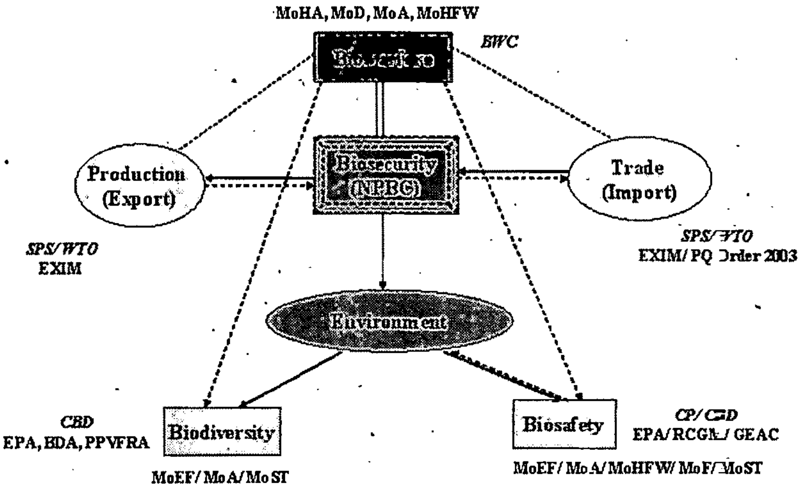
In the light of various issues as highlighted above, a holistic concept to address the issue of biosecurity needs to be evolved. Internationally, the Agreement on the Application of Sanitary and Phytosanitary Measures of the WTO, governs SPS measures in relation to international trade. The Codex Alimentarius Commission (Codex), the IPPC and the Office International des Epizooties (OIE) provide international standards for food safety, plant health, and animal health, respectively. Further, the Cartagena Protocol of the Convention on Biological Diversity (CBD) applies to the transboundary movement, transit, handling and use of Living Modified Organisms (LMOs). Guidelines on the management of invasive alien species have been developed under the SBSTTA (Subsidiary Body on Scientific, Technical and Technological Advice) of CBD.[16] This group of international agreements, organizations and programmes are part of a loose international framework for biosecurity, and reflect the sectorial approach to regulate this area.

It is also clear that under the present international scenario, the plant protection specialists have a major role to play not only in promoting and facilitating export and import in the interest of their respective nations but also in protecting the environment from the onslaughts of invasive alien pests and unforeseen ill-effects of the introduction and trading in GMOs. Besides, the threat to national biosecurity from the use of such instruments as bioweapons to create agro-terrorism is a possibility that requires preparedness. It is because of these reasons that the FAO has recognized the growing importance of biosecurity, and has included it as one of its sixteen Priority Areas for Inter-disciplinary Action. Biosecurity was also included in the Medium Term Plan which aims at "promoting, developing and reinforcing policy and regulatory frameworks for food, agriculture, fisheries and forestry" (http://www.fao.org.COAG/2003/9.htm).

At the national level efforts are being made for the development of a coherent biosecurity strategy for the country. A number of meetings have recently been held to discuss the issue and during one such meeting held recently at the National Institute of Advanced Studies, Bangalore, it was highlighted that there was a need for "convergence in the efforts of all departments and ministries" to develop a coherent biosecurity strategy.[17] It was also emphasized that education, regulation and social mobilization were the three pillars necessary to formulate a biosecurity strategy.[18]

The holistic approach to ensure biosecurity seeks to use the synergies of various existing sectors at the national level, without necessarily creating new structures. It further recognizes the need for integration of various aspects of biosecurity and the institutions involved. There is a need to establish a National Plant Biosecurity System comprising a National Plant Biosecurity Centre (NPBC) to deal with plants, animals, living aquatic resources, and agriculturally important microorganisms as its four major Divisions with the Ministry of Home Affairs (MoHA) at the helm of affairs. MoHA has the National Disaster Management Authority that can properly monitor and regulate the biosecurity issues. Besides, MoHA is also the nodal point of the National Crisis Management Plan 2003. Therefore, if we have to put in place an effective biosecurity system in future, it has to be under the MoHA so that matters related to both biosecurity and bioterrorism (agroterrosim) can be dealt with more effectively and the funds can be invested in the right direction. The emergency action plan and the rapid response team that are critical in the outbreak of an epidemic also needs to be with MoHA. The MoA in its Indian Council of Agricultural Research (ICAR) has excellent researchers and laboratories in the field of plant protection, which would support and work in a networking mode for diagnostics and control of diseases/ pests in the case of emergent situations. Hence, a network of various ministries like MoA, MoEF, Ministry of Health and Family Welfare (MoHFW), Ministry of Defence (MoD), Ministry of Food (MoF) and Ministry of Science and Technology (MoST) could work in close collaboration with the MoHA.

Figure 1: A Holistic Model for National Plant Biosecurity System



(After Khetarpal and Gupta, 2006c)

A holistic model depicting the components of biosecurity including biowarfare, production, trade, environment (biodiversity and biosafety) as proposed recently is given in Figure 1.[19] It also shows the regulatory mechanism including various committees in place at the national level [Export Import Policy (EXIM), EPA, Biological Diversity Act (BDA), Protection of Plant Varieties and Farmers Rights Act (PPVFRA), RCGM and GEAC] for implementation of the international agreements [Biological Weapons Convention, CBD, Cartagena Protocol (CP) and

SPS/ WTO]. The various stakeholder ministries involved are also depicted in the Figure. A coordinated effort and synergy is all that is required to institute an effective biosecurity system in the country.

Models to rationalize regulatory functions among sectors in a quest for improved effectiveness and efficiency have appeared in a number of countries. For example, New Zealand has a Biosecurity Act since 1993 and a Biosecurity Minister and Council since 1999. In the US, the Department of Homeland Security was created in 2002 with as many as 22 agencies including the US Department of Agriculture's Animal and Plant Health Inspection Service. Likewise, the Australian Government has established Biosecurity Australia. In Belize, food safety, and animal and plant quarantine and environmental issues, are dealt with by a single authority, the Belize Agricultural and Health Authority. For a biosecure India, what we need is a synergy of expertise from various organizations under the Ministries of agriculture, environment and forests, food, science and technology, home affairs, commerce and industry and defence. More so, we need the political will.

Endnotes

[1] Khetarpal et al., 2001, Khetarpal, 2004, Gupta et al., 2005.

[2] Khetarpal and Taneja, 2006.

[3] Anonymous, 2007.

[4] Lele and Khetarpal, 2005.

[5] Khetarpal et al, 2005.

[6] Khetarpal and Gupta, 2006b.

[7] Khetarpal et al., 2004.

[8] Chakravarty et al., 2005.

[9] Khetarpal, 2005.

[10] Singh and Khetarpal, 2005.

[11] Khetarpal et al., 2001.

[12] Khetarpal and Pandey, 2001.

[13] Khetarpal and Gupta, 2002.

[14] Gupta et al, 2002, Gupta and Khetarpal, 2004.

[15] Dev et al., 2005.

[16] Rana et al., 2004, Khetarpal et al., 2006.

[17] Khetarpal and Gupta, 2006c.

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Biotechnology Inventions and the Patent Regime

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Abstract: The primary purpose of this paper is to argue that the patent regime for biotechnology may accept patenting fragments of knowledge with the proviso that the formal knowledge and laboratory tools will be made available to everyone who wishes to develop that knowledge towards a marketable product and that the final product manufacturer would be held responsible for sharing the revenues recovered from the market with all the pioneers that contributed to the knowledge development and transfer. This may be, for example, proportional to the costs incurred at successive stages. Such a policy would ensure rapid diffusion of knowledge and technological development while leaving sufficient returns to innovators discoverers at each stage of knowledge accumulation.

Keywords: Biotechnology patents, open source licensing, access to knowledge.

Introduction

The fundamental basis of all developments in biotechnology is the recognition that protein is the key element of all living cells. The earlier chemical-based technologies were directed to understand the chemical structure of proteins, their synthesis, and industrial level production through a fermentation process and other techniques. The classic example is the production of penicillin during the Second World War. The novelty of biotechnology comes from discoveries of the processes by which living cells produce specific proteins to lead cell functions and to create a particular biological activity. In other words, the utilization of chemical processes observed in nature, replaces conventional chemical analysis. These discoveries also make it possible to use bacteria or other genetic manipulations to alter biological activity and in the end clone and produce specific organisms entirely in a laboratory and on an industrial scale.

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The tasks are extensive and each step of the discovery has been very difficult. Part of the reason is the constraint in using two dimensional images obtained through X-ray crystallography and (NMR) scans to identify the three dimensional structure of the protein molecules. Similarly, understanding a vast array of cell functions in the human body or even in plants is a challenging task. As a result, discoveries in biotechnology proceed in a fragmentary way. Only a few cell structures were recorded with difficulty. Examples of this nature are genetically modified cell lines that produce MAbs for diagnosis of diseases and genome data bases that combine sequence data with protein structure. This is typical of scientific progress in all areas of technology and not really specific to biotechnology as such. In general, such fragmentary knowledge must be accumulated and developed toward an ultimate product of use to society. For example, enriched vitamin A rice (popularly called the golden rice) is based on technology that spans 70 patents held by 31 different organizations.

In the past, scientific knowledge was considered a pure public good and made available to anyone who wished to use this to advance it further. Similarly, the universities trained young scientists in the new discoveries and technologies. The private firms then used this pool of talent to implement the technological breakthrough. Similarly, a few years ago, the legalities of obtaining samples of microbes and animals were straight forward. In many instances one could simply arrive at a field site, collect samples, and take them without bothering about legal issues. Samples could be transferred anywhere in the world. It is not possible in today's commercial world. Part of the reason consists in the high costs of R&D and the increasing awareness that knowledge developments at every level have a commercial value.

The issue that had to be addressed is this: what are the most efficient institutional mechanisms to generate R&D, create extensive diffusion of knowledge, preserve the rights of intellectual property, and compensate the pioneers for their discoveries? The most commonly used institutional mechanism is patents. Article 7 of the TRIPS agreement states the objective as,

> "the protection and enforcement of intellectual property rights (with the objective of contributing) to the promotion of technological innovation and to transfer and (disseminate) technology, to the mutual advantage of producers and users of knowledge and in a manner conducive to social and economic welfare, and to balance the rights and obligations".

The basic objective of the rest of the paper is to examine the different institutional mechanisms utilized in practice, to evaluate them with respect to their ability to generate knowledge diffusion and recovery of costs of R&D. The primary contention of this paper is to analyse the efficient patent regime with the proviso that the formal knowledge and laboratory tools will be made available to everyone who wishes to develop that knowledge towards a marketable product, and second that the final product manufacturer shall be held responsible for sharing the revenue recovered from the market with all the pioneers that contributed to the knowledge development and transfer. In the next section, we look into some of these issues.

Biotechnology Patents and Access to Knowledge

Much of the knowledge development, in various scientific activities, was traditionally considered as a public good. This was generally a result of two features. First, most of the scientists, especially those associated with universities had recognition, rather than commercialization, as their primary objective. Second, adequate public funding, in particular for defense related projects, was available. However, over the years, there was no significant involvement of the government in biotechnology R&D primarily because it did not contribute to such defense needs in any major way. Thus, even in the 1960s, secrecy, confined to one research laboratory or a small network of related scientists, was the dominant organizational mechanism. Watson's book, *The Double Helix*, has a graphic description of this approach. The basic reason for this was that a great deal of this fundamental research could not be associated with any product from which the consumers derived value. Secrecy was the only protection for their proprietary knowledge because the patent laws at that time applied the utility doctrine, i.e., usefulness of information to consumers of goods and services as a precondition for the grant of a patent. In the absence of patent protection, secrecy was the best approach to exclusivity. However, during the early phases of biotechnology research, secrecy was perhaps a result of academic competition instead of any commercial interest.

In the context of several technologies, that are not related to biotechnology, the published formal knowledge was adequate for others to reproduce it and create the materials needed to use it. Fundamentally, there was no specific necessity for the original scientist to participate in the knowledge transfer. Similarly, there was no transfer of any physical materials and laboratory tools along with the knowledge. Biotechnology developments are different in both these respects.

As a result, the developments in biotechnology were proceeding in a fragmented way. Both these features rendered further progress towards a protein structure or a marketable product difficult and inefficient due to secrecy. Removal of findings (e.g., nucleotide sequences) from the public domain restricted development of derivative knowledge necessary to make the genetic information practically usable. Bottazi et al. (2001) noted a further complicating aspect of knowledge generation and transfer. As they pointed out, pharmaceutical inventions are such that imitative product development (reverse engineering, generic drugs) is not very difficult and imitation costs are extremely low in comparison to the inventor's costs. Knowledge erosion is relatively fast since new ideas are generated all the time. These features make advances in knowledge weakly appropriable from the viewpoint of the innovating firm. In particular, any mechanism that rewards only the final product discovery does not compensate the contribution of early innovators which is essential to achieve the latter stage developments. This is the crucial aspect of cost recovery in the context of biotechnology firms.

As with any other innovative endeavour there is no guarantee that every R&D effort will succeed. For instance, biotechnology products may fail at the regulatory stage. These risks, coupled with high costs, necessitate protection at every stage of the value chain. It was the necessary to conceptualize an alternative organizational mechanism that would allow fast and efficient knowledge transfer.

The only well-known organizational mechanism to achieve these ends, viz. achieving efficient knowledge diffusion while providing a means of recovering costs, was patents. There was some precedence that pointed towards this alternative. First, as far back as 1911, the learned judge Hand upheld a patent on human adrenaline made by using a new process. The patent was not simply for the process but also the purified substance. Second, in 1975 Kohler and Milstein discovered that individual immune system cells, that generate antibodies to a specific antigen, can be fused with immortal cancer cells to create a small factory for producing antibodies. They did not patent it. Hybritech was the first to use monoclonal antibodies in diagnostic kits sold to doctors and hospitals to identify the presence of diseases (e.g. AIDS) or elevated hormonal levels (e.g., pregnancy tests). It received a patent covering the whole family of diagnostic kits. Patents generally provide a 20-year exclusive market protection if the following conditions are satisfied, viz. novelty, non-obviousness and full and complete disclosure so that anyone knowledgeable about the trade can reproduce the production process. In practice, patent claims should also specify their scope. That is, claims should define what the inventor considers to be the technological territory that he claims to be under his control by suing for infringement if necessary.

Note, however, that biotechnology patents cover three types of matter, viz.,

- Products of biotechnology (e.g., seeds, drugs, diagnostic kits);
- Methods and processes of making the biological matter (e.g., fermentation, gene splicing, methods of controlling pests);
- Uses of biological matter (living or non-living) (e.g., antibodies, enzymes, DNA molecules).

The basic problem in granting patents was that much of the biotechnology knowledge was not directed to products of end use. Other objections to patenting genes were:

- They are discoveries (identifying something that already exists) and not inventions;
- Products of nature are not new;
- The basic core of humanity should not be owned by anyone as property.

However, two 1980 decisions of the U.S. Supreme Court changed all that. The Diamond vs. Chakraborty case was about patentability of a genetically modified bacterium. The court held that such material is patentable because there is novelty. Subsequent, gene or DNA patents have claims that they cover nucleotide sequences that encode genes or fragments of genes. For example, Human Genome Sciences in the U.S. claimed a patent for a gene though its function was not known. It was only asserted that it will be a research reagent or material for diagnostics. Subsequently it was discovered that it was the docking receptor CCR5 used by the HIV virus to infect a cell. Similarly, the U.S. Supreme Court ruled that genetically altered life forms require patenting. A decision by the court allowing an oil company to patent an oil eating microorganism set a precedence and opened up massive possibilities, including that of the exploitation of genetic engineering for commercial purposes. Lakshmikumaran and Pillai (2005) pointed out that the Calcutta high court decision in the Dimminaco A.G. vs. Controller of Patents and designs had a similar basis.

In general, biotechnology patents cover all three types of genetic materials alluded to above. They consist of a combination of definitions of new processes, methods, and compositions. In other words, some genomic discoveries have been granted patents solely on the basis of the new composition or sequences of random pieces of genetic material without knowing its function but only in the hope that it will constitute an important part of a gene. Genetic patents may also be directed to devices for use in testing and diagnostic kits. The pious hope was that patenting knowledge would accelerate its diffusion, help firms obtain finances from venture capital and other sources, and create socially beneficial R&D.

The enlarged scope of biotechnology patents creates a host of new problems. Consider the possibility that a patented biotechnology material requires further improvement and processing before any final product of commercial use emerges. The most obvious example is the Cohen-Boyer patent on rDNA. If another firm wishes to pursue this activity it needs a license from the patent holder. The patent holder may license the use of his patent to others for an appropriate payment. Usually such arrangements have been referred to as material transfer agreements. However, a patent holder may hold rivals hostage if they need licenses for a large number of nucleic acids. For instance, the development of a medicine may depend on genomic technologies, receptors, assays, and high throughput technologies. This phenomenon is usually designated as patent thickets. It tends to increase the transaction costs of reaching agreements with various owners of the components needed to proceed with product development. The costs may increase prohibitively since each of these patent holders claims a royalty. Property rights generally consist of a right to own and a right to use or rent it to others alongwith a right to modify.

Implicitly such property rights allow the owner to exclude others from the use of such property,

- if he so chooses, and
- if others are not willing to pay the rent specified.

The present day patent regime confers these property rights. However, note that such property rights applied historically to final consumers. The question now is: Should any or all these rights apply to knowledge development as well? Article 27.3 of the TRIPS agreement allows governments of sovereign countries to exclude certain types of inventions from patents if national interests are at stake. That is, one extreme form of reaction is to deny such patent rights altogether. This results in secrecy and hinders knowledge diffusion.

In some cases, like the National Institute of Health in the U.S., the agency stipulates that they will not allow certain types of discoveries of fundamental knowledge to be patented. In the absence of an objective way of classifying different types of knowledge development and specifying entitlements, this remains subjective. The question about financing such R&D is also pertinent. However, this may not be a serious issue so long as adequate public funding is available for all such fundamental research. However, over the years, there has been a reduction in the government involvement in biotechnology R&D primarily because it did not contribute to defense needs in any major way. There is a possibility that R&D financed by such institutions would be inadequate. A further objection may be raised even if adequate finances are provided. In particular, the contribution of any one fundamental R&D to the value addition obtained from a final product of utility may far exceed the cost of generating it. Therefore, any knowledge that contributes to such private value addition in the ultimate analysis should be compensated adequately. Public funding institutions may not be in a position to ascertain such value additions *apriori* let alone compensate the innovators adequately. In other words, denying patents *per se* also hinders knowledge generation and diffusion.

Rai (2005a) argues that there is a need for improving access by requiring publicly-funded scientists and research institutions to put data and certain types of research into the public domain or, at a minimum, to license them widely and non-exclusively for a reasonable fees. Non-exclusivity reduces transaction costs and improves the range and quality of resulting products. However, the question of deciding what constitutes reasonable fees cannot be resolved objectively. Further, under the current patent regime, there is no way of compelling private firms to accept exclusivity. Since private R&D constitutes a major portion of biotechnology research this solution is also not adequate.

Some individuals, who patented discoveries, voluntarily agreed to offer non-exclusive access to their knowledge to everyone that may need to use it to move the knowledge forward. The Cohen and Boyer patent for rDNA is one such example. There are two problems with this approach. First, the problem of cost recovery must be resolved. One argument is that in the context of biotechnology mere transfer of formal knowledge will not be sufficient to use it. The scientist, that allows exclusive access to the knowledge he developed, may still charge a consultancy fees for providing the informal knowledge. This may, in itself, be sufficient especially when the use of knowledge spreads widely. Second, there is a possibility that only the manufacturer of a final product sold on the market will usurp all the benefits of the chain of discoveries. Hence, most innovators will be reluctant to use this approach.

Another alternative is to persuade the patent holder to offer his patented knowledge on a collaborative basis or an open source mode. Rai (2005b) makes the case for depending on voluntary action after granting exclusivity. The problem with this argument is as follows. Suppose I am granted a patent with the exclusivity clause in place with a broad scope. Why should I agree to share it free or at a low cost? In particular, a scientist, who is aware that the final product developer is capturing the entire value added, will not accept this arrangement. Rai (2005b) then falls back on the argument that markets in developing countries add very low value to patents. Hence, she feels that innovators can easily be persuaded to provide patented knowledge to them on a non-exclusive basis. But this creates a variety of new problems if firms in developing countries sell their products in industrial countries. Hence, even this approach is not practical.

If none of the above solutions appear practically feasible the only option is to leave the decision, to enforce exclusivity or leave the knowledge as a public good, to the scientists themselves or the institutions that they belong to. However, the current patent regime has already made them feel that they can derive benefits by exploiting the monopoly power granted by knowledge patents. Consequently, it would be unrealistic to expect them to relent. Rai and Eisenberg (2004) alluded to such attitudes of Wisconsin Alumni Research Foundation (WARF).

It would indeed be paradoxical to grant patent rights, with its implications of property rights, and then expect the patent holders to be persuaded that they should allow non-exclusive use of their patent in the larger interest of social welfare.

Evolving an Institutional Approach

For all practical purposes it is by now acknowledged that discoveries of knowledge need protection by applying the utility doctrine with somewhat greater flexibility (not insisting on utility to a consumer of final products). This appears to be a necessity in the context of biotechnology so that the high costs of R&D can be recovered by private individuals and firms that finance such activities. Exclusivity is granted so that the patent holder may claim royalties from those that use their results of R&D. While patent filing released information in the public domain the exclusivity clause has become a hindrance to knowledge diffusion. Several observers argued a case for narrowing patent rights to restore parity. See, for example, Abrol (2005), Correa (2005), Rangnekar (2006), and Rai (2005b). However, as noted in the previous section, only Rai (2005 a,b) has some analysis of alternatives.

Two situations are conceivable. First, there may be a cumulative chain of 'n' inventions before a final product emerges. Second, a new R&D effort, may be at the downstream level, may require knowledge embodied in 'n' earlier patented innovations that are not interrelated in the above sense. The requirements of knowledge diffusion in these two cases are somewhat different.

In the first case each stage of invention can be considered as a different marketable product. The patent holder may then be allowed to negotiate a license to a user at the downstream level and extract rents based on the perceptions of the two parties regarding the value added in that particular use. Similarly, he may grant licenses to many firms pursuing different types of applications and developments. However, in line with the conventional patent regime, the patent holder's rights should be deemed to have been exhausted after the first stage license. This reduces the burden of negotiating a license with all the early down stream innovators.

The main advantage of this approach is in allowing faster diffusion of knowledge. It also reduces the burden of transaction costs on the final stage innovator. Clearly, the patent holder at each stage may negotiate the license based on their perception of the value that their knowledge contributes. The only disadvantage is that early stage innovators may not be in a position to assess the ultimate market value of their innovation. Will the patent holder not grant licenses to competitors pursuing the development of the same marketable product? There may be some short-run difficulties. However, long-term reputation will be at stake if such moral hazard persists. Hence, it is unlikely in the long run.

A second approach is more practical and is necessary in the second context. It can also be utilized in the first case. Begin with the observation that the innovator at the final product stage can recover costs when a marketable final product is available. The licensing contract for upstream knowledge is similar to subcontracts for parts and franchise bidding in any other industrial context. Confronted with risks in the ultimate product market the upstream firm may either choose the rents *ex ante* to resolve the risk on wait for the risk to be resolved *ex post* and claim returns accordingly. More often than not, the latter choice is more efficient and it can be implemented if knowledge about the market is not difficult to verify. This suggests the following modification to the patent regime. Suppose that the system of patenting knowledge is continued with two conditions. one, each of the early stage innovators will be under obligation to provide the knowledge on a non-exclusionary basis. Two, the entire chain of related innovators must be compensated if and when later stage R&D results in a marketable product. This accelerates knowledge diffusion while preserving the appropriability of intermediate discoveries of knowledge. The practical problem of apportioning the eventual benefits among them can be resolved by making payments proportional to the costs incurred at each stage of R&D development. This generally results in recovering more than the costs involved and is closer to the contribution of any one aspect of knowledge to the ultimate value. Hence, the objections raised in the context of public funding of R&D will not arise.

The patent application must normally specify the territory that the applicant considers his own and thus exclude others from it. Hence, the following subtle points can be introduced. First, he may be required to spell out the developments for which the use of knowledge will be allowed on a non-exclusionary basis. Some examples can be offered, namely (a) The knowledge under consideration is not known to result in any marketable product either within the scope of the patent or outside of it. (b) In some cases there may not be any market for early knowledge developments because utility is not obvious. Second, there may be some parts of scientific knowledge that he considers far removed from a final product. In such a case he may be asked to specify the parts of knowledge that he will exclude unless a payment is made.

On the whole, as in the established practice, accepting full property rights for products of utility can be justified. However, they should not apply to at all stages in the context of knowledge development. Otherwise the pious hope that patents will result in extensive knowledge diffusion will not materialize.

Recommendations

However, in general, it must be noted that the new model will be usable only if the patent application contains information about all the prior patented knowledge utilized in the downstream development. It is also necessary for every scientist, at the intermediate stages of development, to declare the costs of their R&D. From an operational viewpoint there may be a necessity for some institutional mechanism to ensure that payments are properly made and redress grievances if they arise.

An objection to the new scheme may still arise. Note that under the present patent regime a scientist can claim payments as early as possible. What then is the incentive for him to wait until some final product of utility is marketed? Two points may be recorded as possible answers to this question. First, it is well known, from the economic theory of incomplete contracts, that such *ex ante* resolution is inefficient under conditions of risk. Second, under the present patent regime there will be fewer users and/or uses of knowledge that the patent holder developed. This is primarily due to the costs that must be paid before the value is realized and the extensive transaction costs. When the new model is in operation, there will be widespread knowledge diffusion and a better chance of value enhancement. Hence, the losses due to the time lags may be more than compensated. However, it must be acknowledged that this is an empirical matter that any *apriori* judgement about the superiority of one over the other may not be warranted.

Many observers of the current patent regime applied to biotechnology developments acknowledge that exclusivity rights implicitly granted by patents have been a hindrance to knowledge diffusion and enhancement. However, no practical suggestion to overcome this problem has been forthcoming. This paper suggested a practical solution based on the economic theory of incomplete contracts. The new approach requires a slightly more extensive knowledge disclosure from patent applicants. Similarly, there may be an apprehension that the final product manufacturer may not comply with royalty sharing arrangements. In such a case some institutional mechanism to monitor and redress grievances will be necessary. The social cost of such a patent regime may be, however, far less than the welfare gains. It is worthwhile to try it because there will be no problems of patent law in its implementation.

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WTO Ruling on the EU-US Biotech Products Dispute: A Review of Issues

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Abstract: The current paper reviews the future direction of US trade policy on genetically modified (GM) crops. The US has recently won a case at the WTO Dispute Settlement Body (DSB), challenging the EU's *de facto* moratorium on approvals of biotech products as well as the safeguard measures undertaken for that purpose. The DSB ruled the EU policy to be inconsistent with the 'sufficient scientific evidence' and 'risk assessment' requirements under the WTO SPS Agreement. The case law sets a precedent and the US might follow the same route for other WTO members, who are currently not permitting import of GM crops within their territories. It has earlier raised concerns on the policies of several developing countries including South Africa. India, which is yet to approve any GM food crops till date, may also face similar concerns. Considering the current scenario, the paper concludes that India must keep the Cartagena Protocol on Biosafety in mind while developing its legal provisions for GM crops through Food Safety Bills, to ensure the precautionary principle.

Keywords: GM, Cartagena Protocol, US, EU, India, Biosafety, Biotech, Cotton

Introduction

The cultivation of various GM crops (like corn, soya and maize) have expanded in both developed as well as developing countries, especially in Argentina, Canada, China and the US, with a consequent increase in the export interest. However, the EU decision in mid-1999 on not allowing marketing of any new GMOs there before updating the EU rules, to satisfy public concerns about possible dangers to human health and the environment, caused the US farmers to complain about a sales loss of US $300 million (172 million pounds) per year in the EU markets and elsewhere indirectly as a consequence (Crop Choice, 2002).[1] In

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May 2003, the US moved the WTO dispute settlement body against the EU's *de facto* moratorium on approvals of biotech products and individual member's marketing prohibitions on previously approved biotechnology products (DS 291). Canada (DS 292) and Argentina (DS 291) also joined the dispute. The complaints alleged a violation of Articles 2, 5, 7 and 8, and Annexes B and C of the SPS Agreement and Article 4 of the Agriculture Agreement among other provisions. Suppan (2005) noted that any panel ruling in favour of the US would have a profound impact on the viability of successfully using a precautionary principle-based defense. Currently, a number of Indian states are apprehensive about allowing cultivation of genetically modified (GM) crops within their territories. The situation needs to be viewed in the perspective of the current global conflict on GM crops and their implications for India.

Panel Report and Related Dynamics

The concerned WTO panel has delivered its interim report in February 2006 and the final report in May 2006, taking almost two years to complete the case. It concluded that the general *de facto* moratorium and product-specific approval policies of the EC as well as safeguard measures taken by individual Members are inconsistent with the 'sufficient scientific evidence' and 'risk assessment requirements' under the SPS Agreement. It also turned down the EC argument for considering the Convention on Biological Diversity (1992) and the Cartagena Protocol on Biosafety (2000) for interpreting the relevant WTO rules in this case, without providing much explanation.[2] However, the panel ruling has left a number of unresolved questions, for example, the issue of 'likeness' between GM crops and their conventional counterparts, WTO-compatibility of EC's current approval procedures based on a product-by-product assessment; future implications of the panel's narrow interpretation of 'risk assessment' in the SPS Agreement on Member's ability to adopt precautionary approach, etc.[3] Interestingly, the panel accepted, but refused to consider, *amicus curiae* briefs.

The panel decision has created more controversies than it actually solved, with questions being raised on the right of the WTO to decide on this issue claiming that every country should be free to decide the required level of protection for its environment and health.[4] In the light of the panel findings, we try to understand what a possible US response to this might turn out to be. The driving impetus for the US to lodge the case at WTO has been its market losses at the EU. The US has so far raised concerns on the GM policies of several countries. Table 1 provides a brief summery of its views on that front.

Table 1: Biotech Policies of Select Countries – US Viewepoint

Country	Concern
Brazil	On March 2, 2005 Brazil approved a Biosafety Bill, replacing the previous legal framework in use since 1995. Despite creating a framework for judicial proceedings under the new regime, some unresolved issues like application of the labeling regulations for biotech products, marketing and transportation restrictions in some states, widespread piracy of (biotech) soybean and cotton seeds, etc. still remain.
China	In January 2002, the Ministry of Agriculture (MOA) issued new regulations on agricultural biotechnology safety, testing and labeling; affecting imports of soybeans, while corn, etc. As the rules did not provide adequate time for completion of required safety assessments, China issued interim rules, extended twice, which allowed trade to continue while authorities carried out safety assessments of biotech products. Although subsequently China has approved varieties of soybeans, cotton, corn and canola events, US is still concerned about the procedural framework, e.g. - limited timelines for submission of products, lack of clarity on assessment requirements for stacked (multiple trait) products, duplicative and unprecedented testing requirements, apparent lack of coordination of the development of biotechnology policy in China, etc.
EC	In April 2004, EC Regulations 1829/2003 and 1830/2003 governing the approval, traceability and labeling of biotech food and feed were brought into force, requiring mandatory traceability and labeling for all biotech and downstream products, indicating whether the food is different from its conventional counterpart in composition, nutritional value, etc. The rules requires the operators to introduce a standardized system for maintaining information about biotech products and to identify the operator by whom and to whom it was transferred for a period of five years from each transaction.
India	Given the absence of a policy framework for assessing the safety of biotech commodities and foods, the decision-making process is considered slow, non-transparent and arbitrary, which equally hampers the domestic research on agricultural biotechnology.

Table 1 continued

Table 1 continued

Country	Concern
Indonesia	In early 2001, Indonesia has introduced labeling requirements for GM food products ('genetically engineered' and irradiated' ingredients), although the government is yet to implement them owing to the absence of established minimum threshold limits. The estimated approximate trade loss of US soybeans and soybean meal would be $411 million annually in the regulations come into effect.
South Africa	The GM Organisms Act was introduced in 1999, and further complemented by labeling regulations on biotech products in early 2004, making labeling of foods containing agricultural biotechnology, proof of enhanced-characteristic of it and establishing significant difference from a non-biotech equivalent mandatory. The use of biotech products is widespread in food processing industry, and the government published draft changes to make the GMO Act compatible with the Cartagena Biosafety Protocol in November 2004. However, the requirement of *de novo* review involving "stacked events" by considering it a new product, unlike a conventional one in the US is a problem area.
Sri Lanka	Ongoing discussions for introducing a labeling requirement for GM food imports are a major concern area and the Ministry of Health has drawn up a draft law for regulation purposes.

Source: Constructed with the help of USTR (2006).

A changing perspective in the EC is being observed recently. On 24 June, 2005, the Environment Council rejected the eight Commission proposals to lift the safeguard measures imposed by five Member States against biotechnology maize. Interestingly, 22 out of 25 Member states voted against the lifting of the bans; only the UK supported the Commission on all proposals, while Sweden and Finland abstained[5]. However, a number of Member States have now drafted new laws, for ensuring the co-existence of biotechnology and conventional crops, or have chosen to provide industry guidance. Moves to review the present decision-making process on biotechnology approvals are also observed.[6] Therefore, increasingly the US focus is likely to be on other countries from now on as well.

The US has already raised concerns over the South African policies for grains producers wherein the approval for biotech products involving "stacked events"[7] treat combinations of two previously approved genetic modifications as a "new" variety rather than as "conventional" as in the US. This significantly delays the registration process there. Also the US has voiced concern over the non-approval of US yellow corn for importation in South Africa because of "stacked events".[8] Other African countries (for example, Zambia) have earlier rejected US food aid mixed with GM crops.[9] Chances are high that now the US might push African countries to accept GM crops, although several Africans countries are in no mood to comply with such pressure.[10] Among Asian countries, in 2001, Sri Lanka decided to put an outright ban on GM crops, but the US got the ban overturned by threatening to impose restrictions on imports of Sri Lankan tea (Global Week of Action, 2004). The WTO also asked Sri Lanka to give its trading partners 60 days to prepare for the restrictions.[11] In 2003, the US seriously considered the possibility of dragging Sri Lanka, Bolivia and Croatia to the WTO DSB over their GMO regulations.[12] In this context, the GM policies of India and their implications on consumer interest should be carefully assessed.

Indian Scenario

India has earlier rejected food aid of corn-soya blend from the US fearing that it may contain a GM strain.[13] While the EU and several African countries are very particular about labeling, in contrast in the US no special treatment is necessary, as these products are not segregated from their non-GM counterparts under local regulations. The US regulatory agency did not issue any certificate to specify that the corn-soya blend shipment did not contain any banned or obsolete variety of transgenic corn in a context where the Indian Council of Medical Research (ICMR) expressed its opinion against feeding GM foods to vulnerable populations. The Genetic Engineering Approval Committee (GEAC), a regulatory body working under the Ministry of Environment and Forests, therefore rejected the food aid.

India has not approved any GM food crops yet, although many such varieties (e.g. - transgenic rice, GM mustard, GM potato) are currently under various stages of development. During the last couple of years, field trials for various GM crops have been undertaken.[14] Approval for commercial production of GM cotton (Bt cotton), developed by Monsanto of the US was given after several years of field trials. It is likely that the government might approve large-scale field trial of GM brinjal, mustard and potato soon prior to their commercial release / marketing.[15] One major reservation against the use of GM crops imported from other countries, apart from the human health risk, has always been that the crop might affect the local environment adversely. For instance, the pollen and seeds from GM crops may be transmitted to their non-GM varieties cultivated in nearby fields, and the passing of genes can create stronger weeds. As a consequence, farmers might resort to more damaging chemicals to curb them. In contrast, the nutrition value of the GM crops is highlighted at times.[16]

A changing Indian perspective is noticed in the recent period, as the GEAC has allowed imports of refined soyabean oil extracted from GM crops without any tests, provided it is accompanied by a certificate from the exporting country declaring its GM link.[17] The Foreign Trade Policy (2006) announced that all imported GM products should be labeled.[18] The health ministry subsequently was engaged in finalizing rules relating to the labeling of GM food. To facilitate finalization of the labeling norms, the Ministry of Commerce had kept on hold laws relating to the mandatory labeling of imported GM products till 7 July, 2006.[19]

Concluding Remarks

It has been argued that harmonization of the different policies and regulations formulated by different ministries are an essential prerequisite for ensuring the effective governance of biotechnology.[20] The recent Food Standards and Safety Bill 2005, proposed the setting up of an independent food authority, in line with the recommendations of Swaminathan and Mashelkar Committees, for regulating all laws pertaining to GM foods. Once the Bill is passed by Parliament, rules relating to the labeling of GM food would thereby be reviewed and administered by an independent food authority. However various quarters have already voiced concerns over the plans to dismantle the GEAC.[21]

In the near future, the regulatory aspect of GM crops in India will gain importance. The recent Supreme Court decision rejecting Monsanto's plea to put a stay on the Andhra Pradesh government order directing the company not to charge over Rs. 750 on a 450 gram packet of its GM Bt cotton seeds is only the beginning.[22]

Finally, one must note the possible implications of the "Cartagena Protocol on Biosafety" in future disputes as it highlights the precautionary principle for developing an international environmental agreement.[23] India must give importance to this principle while developing its legal provisions for GM crops through Food Safety Bills. The independent Food Authority while passing on its views should have a binding commitment to ensure the precautionary principle as highlighted in the Cartagena Protocol.

Endnotes

[1] According to USTR (2006) in 2004 in Portugal itself the regulations caused losses of $56 million and $21 million for corn and soybeans, respectively.

[2] Sharma (2006e).

[3] Bernasconi-Osterwalder and Oliva (2006).

[4] Beattie, (2006); Greenpeace (2006).

[5] Greenpeace (2006).

[6] USTR (2006).

[7] If two different traits obtained by genetic modification are combined by breeding, the final product is termed as 'stacked event'.

[8] USTR (2006).

[9] Lobe (2003).

[10] Shacinda (2006).

[11] ICTSD (2001).

[12] Baumüller (2003).

[13] Luce (2003); Indian Express (2003); Devraj (2003).

[14] Srivastava (2002).

[15] Sharma (2006d).

[16] Jagannathan (2004); Planet Ark (2004).

[17] Sharma (2006c).

[18] IEPORT (2006).

[19] Sharma (2006a).

[20] Chaturvedi and Chawii (2005).

[21] Bharat Krishak Samaj (2006).

[22] Sharma (2006b).

[23] Baumüller (2003).

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Document

Asian Biotechnology, Innovation and Development Initiative (ABIDI)[*]

During the Third Asian Conference on Biotechnology and Development at Manila on 9-10 November, 2006, it was that Asian countries should launch an initiative to evolve an analytical framework for policy makers in the area of biotechnology. The idea is to collect policy relevant statistics for analysing trends in investment, public allocation, availability of manpower and activities of the private sector. This should be done in the context of overall socio-economic requirements in the region.

Adoption of biotechnology in industrial and other activities is a relatively recent phenomenon even in many developed countries. It is expected that the statistics would provide clarity about the governance of biotechnology. It is, therefore, important to outline a statistical framework that allows the measurement of these industrial and developmental activities so that the policy makers may evolve adequate responses. Since in a globalized world innovation is influenced by several interdependent regional systems hence, it would be useful to launch this initiative at the Asian level.

In this note, we first give a brief account of the ABIDI initiative followed by a definition of biotechnology and then of the data collection system in the OECD. We also try to evolve a modified biotechnology statistics framework mainly in terms of commercialization of GMOs, R&D allocations and industry statistics. The last section gives an outline of a possible plan for adoption of statistical indicators for data collection.

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[*] Background Note prepared for ABIDI meeting on 25 January, 2007at New Delhi.

The ABIDI Initiative

Asia has seen a sharp rise in the biotechnology industry in the last decade. The wide-ranging applications of biotechnology in the spheres of pharmaceuticals and agriculture have made this not only an instrument for addressing certain key development issues like food security and health care but it has also emerged as a catalyst for economic growth. No wonder the developing countries have shown great interest in the new technology and the biotechnology industry today has a growing presence in the industrial sector of these countries, particularly in those from Asia.

However, there have been no systematic efforts to put together quantitative details of these advancements. The quantification of various initiatives, at an internationally comparable level could have provided a precise estimation of complementarities that exist in the Asian region for cooperation and also for supplementing national efforts for optimum utilization of available resources. Similarly, there are several issues that deserve the attention of policy makers and researchers for understanding the direction of the S&T policy and its impact on society at large. It is against this background that the ABIDI initiative is being launched.

The idea is to bring together policy community, academics and interested institutions for facilitating greater understanding on the policy aspects related to the innovation and development of biotechnology. The issues related to ABIDI that we wish to discuss in this meeting may be summarized as follows:

(a) Organizational structure or nature of agencies to be encouraged for collection of biotechnology statistics at the national level,

(b) How convergence would be achieved in the methods of collection, authentication and curing of data across countries,

(c) The publication of comparable results at the Asia level would require some resources and an international institutional support not only for financial resources but also for analytical inputs. It is also to be seen whether ABIDI would remain web based or would publish these statistics,

(d) Another important issue is to see the focus of the survey, that is, to see which among these indicators would be incorporated and what would be the frequency of these surveys, and

(e) Selecting of a modalities for the initiative for its smooth working.

Definition of Biotechnology and International Initiatives for Collection of Biotechnology Statistics

To maximize comparability of both public and business sector biotechnology statistics, a definition of biotechnology was developed by OECD with the help of an expert group. There are two definitions the OECD came out with. These were updates that were consequent to the field-based experience in some countries.

The first defines biotechnology as *"the application of science and technology to living organisms, as well as parts, products and models thereof, to alter living or non-living materials for the production of knowledge, goods and services."*

Although the single definition defines the purpose of biotechnology, the list-based definition is essential for identifying modern biotechnology. In the *Biotechnology Statistics 2006* report, the OECD includes data for a few countries that used a different definition of biotechnology, as long as the definition was limited to 'modern' biotechnology. This option will still be available in 2008, although we encourage countries to adopt the OECD definition.

OECD list-based definition of biotechnology techniques

DNA/RNA: Genomics, pharmacogenomics, gene probes, genetic engineering, DNA/RNA sequencing/synthesis/amplification, gene expression profiling, and use of antisense technology.

Proteins and other molecules: Sequencing/synthesis/engineering of proteins and peptides (including large molecule hormones); improved delivery methods for large molecule drugs; proteomics, protein isolation and purification, signaling, identification of cell receptors.

Cell and tissue culture and engineering: Cell/tissue culture, tissue engineering (including tissue scaffolds and biomedical engineering), cellular fusion, vaccine/immune stimulants, embryo manipulation.

Process biotechnology techniques: Fermentation using bioreactors, bioprocessing, bioleaching, biopulping, biobleaching, biodesulphurization, bioremediation, biofiltration and phytoremediation.

Gene and RNA vectors: Gene therapy, viral vectors.

Bioinformatics: Construction of databases on genomes, protein sequences; modelling complex biological processes, including systems biology.

Nanobiotechnology: Applies the tools and processes of nano/microfabrication to build devices for studying biosystems and applications in drug delivery, diagnostics, etc.

The Working Party of National Experts on Science and Technology Indicators (NESTI) of the Committee for Science and Technology Policy of the OECD has initiated an exercise in data collection in biotechnology for Member countries.[1] In its various meetings, NESTI decided to initiate the exercise after finalizing the definition of biotechnology for statistical purposes. An inventory of policy issues and related indicators has also been prepared. Different working groups have come out with guidelines for the compilation of these indicators along with model questions and surveys. These working groups are also identifying links with other existing manuals like the Oslo Manual and the Frescati Manual. Some of the Member countries have already launched data collection exercise, which we discuss briefly herewith.

Canada is one of the major economies following the OECD definition of biotechnology. Statistics Canada is currently running its fourth dedicated survey on biotechnology covering almost 12,000 firms, with a revenue of $ 250,000 (Can $) and using 22 different categories of biotechnology, as per the list-based definition of biotechnology prepared by OECD. Canada has come out with an exhaustive model survey with almost 30 questions spread over several pages.[2]

In France, two surveys have already been conducted for the years 1999 and 2000, while the third survey is all set to be launched in the middle of 2002.[3] This survey is to cover 1500 firms engaged in biotechnology. Plans are also being worked out to incorporate the results of these surveys in the Annual R&D survey of France. There are two major government departments in France, viz. the Bioengineering Department and the Bureau of R&D Statistics, which together conduct the biotechnology surveys, since 2001. Before this, the Bioengineering Department was managing its own database of firms entering incubators, awarded by the annual national contest by the firms' creation and voluntary registrations in the national database, while the Bureau of R&D statistics relies on their own surveys. The first in the series was launched in 2000.

In the United States, the National Science Foundation (NSF) of the Department of Commerce has launched a limited data collection exercise of biotechnology statistics.[4] Since 2001, data about biotechnology was being collected as part of the Survey of Industrial Research and Development, as was being done for other technologies like information technology and material synthesis. However, realizing the importance of biotechnology in the economic growth, it has been decided to make Bureau of Industry and Security (BIS) as the lead agency to collect statistics on biotechnology from 2002 onwards. In order to facilitate this exercise, an inter-agency working group has been constituted. This survey would be mandatory in nature.

Similarly, Japan and Australia have also conducted their first limited surveys in the years 2000 and 2001, respectively. Australia has developed the Australian FoS classifications that are relevant to biotechnology.[5] Australia will shortly include FoS in their next R&D survey. The results are expected in twelve months time. Australia will report the results of this survey back to the Ad Hoc group in 2003, which will serve to guide the group as to the final levels of FoS in the future.

Actually, OECD is facilitating the evolution of a common approach towards biotechnology data collection so that international comparison becomes easier. At this point, there are significant differences in terms of approach towards data collection, definition of biotechnology and variables being covered among different OECD Member countries.[6] However, the core 6 issue remains centred around the financial cost, lack of expertise and regulations and finally, the market uncertainty. Canada and New Zealand distinguish four major areas for biotechnology processes namely: (a) DNA-based processes; (b)

Biochemistry and immunochemistry; (c) Bioprocessing, and (d) Environment. The French survey does not distinguish major categories. Within these major categories, several sub groupings are distinguished. These are fairly similar for Canada and New Zealand, and differ somewhat with those identified in France. Similarly, these country surveys approach the question of barriers in adoption of biotechnology in different ways. The Canadian survey requests information on barriers to biotechnology use, whereas the New Zealand survey requests information on barriers to R&D in biotechnology while the French survey does not ask for barriers.

In the *Biotechnology Statistics 2006* report, the OECD includes data for a few countries that used a different definition of biotechnology, as long as the definition was limited to 'modern' biotechnology. This option will still be available in 2008, although we encourage countries to adopt the OECD definition.

Proposed Plan for Asia

In case of Asia, we are beginning the biotechnology statistics collection exercise with the following template.

1. Please list the publicly-funded biotechnology R&D programmes that exist in your country in the table below. For each programme, please provide as much of the information below as possible. Please use another sheet if you have more than three biotechnology R&D programmes.
    1. Name of the key funding agency (ies) dealing with biotechnology
    2. Year of launching of first biotech initiative (both research and commercial)
    3. Generic areas of funding (e.g. Agriculture, Medical, Animal, etc.)
    4. Implementing Agencies
    5. Amount of funding total and approximate funding (US $) during last 5 years
    6. Primary recipients of funding (e.g. private sector, higher education, government research organizations)
    7. Cost-sharing between funding agencies and R&D performers (if any)
    8. Web address (URL) of key government agency dealing with biotechnology.

2. Please provide available official statistics on biotechnology R&D performed or funded by the government. Where possible, please break out funding by type of performer (government, business, higher education, other), by type of application (e.g. health, agriculture, environmental, industry) and by type of instrument used (e.g., institutional funding, contracts or grants).
3. Please provide available official statistics on the estimated number of researchers (or science and technology personnel) in the biotechnology sector. If possible, please distinguish among researchers in the business, higher education and government sectors.
4. Please provide number of private sector companies (if possible sectors-wise distribution and their turnover).

First Meeting of ABIDI

At the informal meeting organized by RIS and Department of Biotechnology (DBT), Government of India, the Asian Biotechnology Innovation and Development Initiative (ABIDI) was launched in New Delhi. The meeting was inaugurated by Dr. Nagesh Kumar, Director General, RIS. The perspectives on ABIDI were discussed by Dr. S. R. Rao, Adviser, DBT. Professor Anthony Arundel of OECD, Paris set the tone for discussion by focusing his presentation on 'Biotechnology Indicators for Public Policy'. Professor Anthony and Ms. Brigitte Vanbeuzekom of OECD also gave an overview on biotechnology statistics collection plan of OECD for 2008-09.

The meeting was attended by Dr Nina Gloriani, The Philippines, Dr Virginia G. Novenario-Enriquez, The Philippines; Dr Prasartporn Smitamana, Thailand, Ms Watcharin Meerod, Thailand; Dr Karim Maredia, MSU; Prof Dongsoon Lim, South Korea; Dr Ann Jinhui, China; Dr Bambang Purwantara, Indonesia; Dr Durga Datta Dhakal, Nepal; Prof Phua Kai Hong, Singapore; and Dr Anil Jayasekera, Sri Lanka.

The Indian participants included Dr K. K. Tripathi, DBT, Dr A. K. Harit, DBT, Dr K. Satyanarayana, DDG, ICMR; Dr V. S. Reddy, ICGEB; Dr Vibha Dhawan, TERI; Mr N. Srinivasan, UNAPCTT while the private sector was represented by Dr A. S. Kataria, Seed Association of India; Dr R. K. Sinha, All India Crop Biotechnology Association and Ms Rolly Duhera, BioSpectrum.

Endnotes

[1] Some non-Member countries like India and Israel have also been involved recently.

[2] Rose (2002). 'Update on the Biotechnology Statistics Programme in Canada'. A paper submitted at the working party of National Experts on Science and Technology Indicators, Finland, 13-15 May 2002.

[3] Francoz, Dominique (2002). 'The State of Biotechnology Statistics in France'. A paper submitted at the working party of National Experts on Science and Technology Indicators, Finland, 13-15 May 2002.

[4] Beuzekom, Brigitte van (2002). 'Update on Biotechnology Statistics in the United States'. A paper submitted at the working party of National Experts on Science and Technology Indicators, Finland, 13-15 May 2002.

[5] Byars, Derek (2002). 'Australia: Identification of Fields of Science Relevant to Biotechnology R&D'. A paper submitted at the working party of National Experts on Science and Technology Indicators, Finland, 13-15 May 2002.

[6] Pilat, Dirk (2002). 'Detail on some key survey questions in biotechnology use surveys'. A paper submitted at the working party of National Experts on Science and Technology Indicators, Finland, 13-15 May 2002.

Select Sites on Agricultural Biotechnology Supporting Institutes

The Agricultural Biotechnology Support Project (ABSP)

ABSP is a USAID-funded project based in the Institute of International Agriculture at Michigan State University. ABSP works with private and public institutions to improve the capacity and policy environment for the use, management and commercialization of agricultural biotechnology in developing countries.
http://www.iia.msu.edu/absp/index-old.html

The National Agricultural Biotechnology Council

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New Arrival

A Simple Guide to Intellectual Property Rights, Biodiversity and Traditional Knowledge

Tejaswini Apte
Kalpavriksh
GRAIN and IIED
Pune / Delhi, 2006. pp. 151

This Guide to *Intellectual Property Rights, Biodiversity and Traditional Knowledge* forms part of the Biodiversity Information Pack produced by Kalpavriksh, GRAIN and International Institute for Environmental and Development (IIED). It presents user friendly information and mainstream debates on IPRs, biodiversity and traditional knowledge. Apte's book is one among the three components of the Biodiversity Information Pack that also includes *A Guide to the Biological Diversity Act 2002*, and *Understanding the Biological Diversity Act 2002: A Dossier.*

The present guide to IPR is an important source of basic information on patents, intellectual property rights, biodiversity and biodiversity related traditional knowledge in a question answer form. Initially, the handbook starts with a set of very specific basic questions pertaining to the layman's query regarding patents, Plant Breeder's Right (PBRs), Copyrights, Trademarks, Trade Secrets, Genetic Engineering, Traditional Knowledge and Biopiracy and what appear to be controversial issues in general.

The introductory chapter clearly reveals the need to understand these controversial issues for advocacy groups, policy makers, activists, academicians, bureaucrats, media persons as well as interested laypersons in order to take a stand in the protection of their interests. There are relatively a smaller number of people in India who are able to fully access and understand these controversial issues and debates around IPRs.

The next section which forms the core of the *Guide* starts by outlining the most basic information regarding biodiversity and its related fields and gradually progresses to more complex issues like bioprospecting and biopiracy. In an insightful way it tackles the prospective implications of these issues for an ordinary citizen while it also brings out the connection between IPRs and biological resources. That IPRs and private monopolies over biological resources and related traditional knowledge can have direct negative effects on India's food security, biological diversity, and on the protection of traditional knowledge is also highlighted. In dealing with these wide ranging complex issues, the handbook presents a store of interesting age old stories linked with the conserved wild areas that are dedicated to local deities, apart from traditional medicinal knowledge of forest products and progresses to modern world wide examples of biopiracy for the reader's understanding of what it involves.

Further, in its two Appendices, the handbook provides the text of various International Agreements and Negotiations relating to IPRs, biodiversity and traditional knowledge. These include for example: Convention on Biological Diversity (CBD), 1992; TRIPS, 1994; International Treaty on Plant Genetic Resources for Food and Agriculture, 2001 (ITPGR); Patent Cooperation Treaty (1970); and Patent Law Treaty (2000); and UPOV 1961 along with the latest revisions. The origins, goals and the main objectives of various international agreements and negotiations have been thoroughly discussed in detail in very clear and simple language. The present *Guide* also throws light on the general weaknesses inherent in these international agreements.

The Guide provides an ample list of references and the names of related website links consulted in preparing the handbook. These provide useful sources for advanced learning in this specific area. The Jargon Buster section breaks through the complicated language commonly used in IPR-related writing, that has a limited readership confinement to the biotech researchers and experts. By extending comprehension of this jargon, it is designed to be a handy reference for common people as it explains words and phrases that commonly occur in IPR-related writing and have been extensively used in this handbook.

On the whole, the Guide gives an in-depth account of the key concepts and debates around IPRs, biodiversity and traditional knowledge in the Indian and international context. For instance, the famous case of Basmati Rice has revealed that a patent was granted to RiceTec, a Texas based company, for new rice varieties derived from crossing semi-dwarf varieties with 22 traditional Basmati varieties from India and Pakistan. However, the patent was revoked after the CSIR, India, requested for re-examination of the patent. Subsequently, RiceTec was even forced to drop the title 'Basmati rice lines and grains'. This case study of Basmati rice is helpful in creating awareness of such issues in the developing countries. Various case studies of biopiracy have been presented in the special boxes to provide useful insights for concerned interested readers. Arguments against unjust IPR regimes, against biopiracy and against the private monopolization of biological resources and related local traditional knowledge are presented lucidly. In the whole, it is a useful guide.

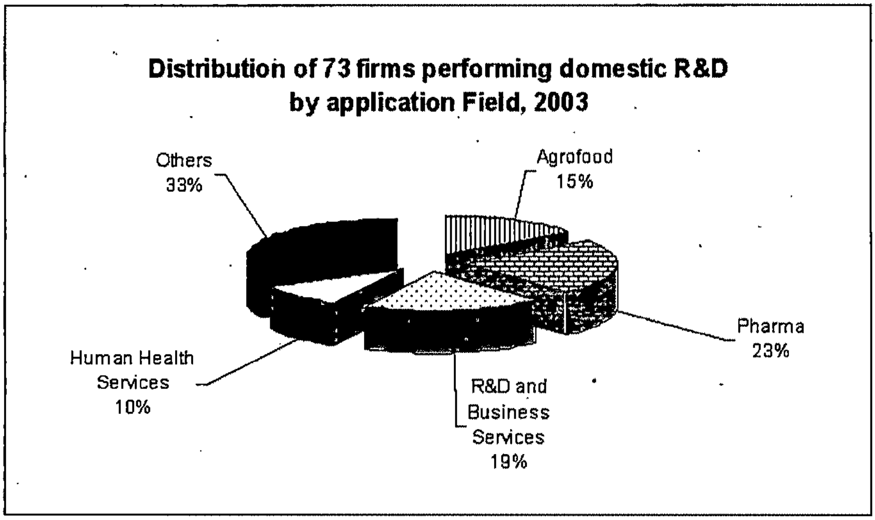
— Beena Pandey

Bio Stat

Biotechnology in Belgium*

In 2003, 73 biotechnology firms were identified in Belgium. The European Classification of Economic activities (NACE) was used to categorize firms into different sectors. These firms were classified into four industrial sectors: Agrofood (a combination of Agriculture, and Food and Beverages), Pharmaceuticals, R&D and Business Services and Human Health Services. There was also an "Other" category. Twenty-four firms (33%) fell in the "Other" category; 17 firms (23%) were classified in the Pharmaceuticals sector; 14 firms (19%) were classified in R&D and Business Services and 7 firms (10%) were in Human Health Services.

Seventy of the 73 biotechnology firms responded to the detailed employment questions in the survey. In 2003, the 70 biotechnology



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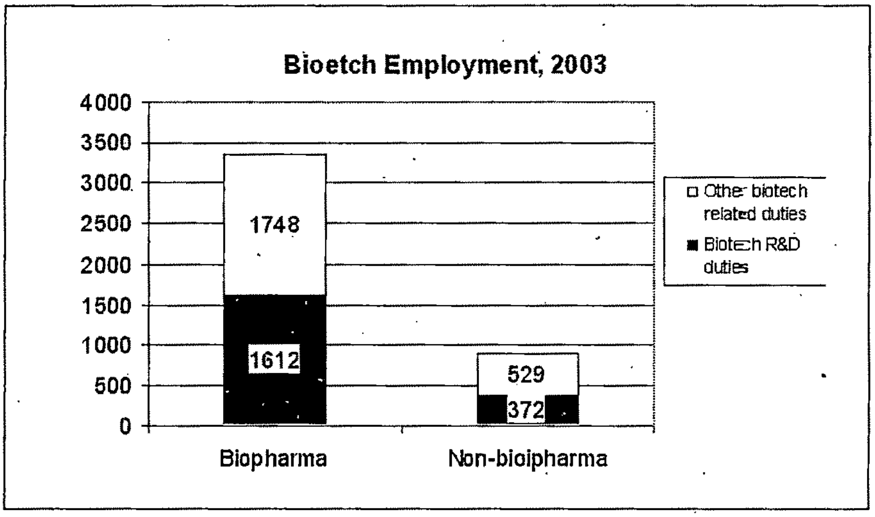
* Based on OECD (2006).



firms employed 11,137 persons. Of these, 4,261 (38%) had biotechnology-related responsibilities, including 1,984 with biotechnology R&D responsibilities (18% of the total employment). A much higher percentage of the total employment in biopharma versus non-biopharma firms had biotechnology responsibilities: 51.5% compared to 19.5%.

Forthcoming Issue

Asian Biotechnology and Development Review

Vol. 10 No. 1 November 2007 ISSN: 0972-7566

Special Issue on Biorefineries: Prospects, Problems and Perspectives for Developing Countries

Guest Editor: Dr Edgar DaSilva

Special Issue on Biofuels and South Asia: Policy Options

Guest Editor: **K.V. Raju**

Vol. 8 No. 2 March 2006 ISSN: 0972-7566

- **Biofuels in South Asia: An Overview**
  K.V. Raju
- **Improved Livelihoods and Environmental Protection through Biodiesel Plantations in Asia**
  Suhas P. Wani, M. Osman, Emmanuel D'Silva, and T.K. Sreedevi
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Domestic Policy Options: International Trends in Liability and Redress

Philippe Cullet*

Abstract: The current paper anâlysis liability regime under Article 27 of Biosafety protocol and compare it with emerging alternatives like Africa model law and safety in biotechnology and Swiss Gene Biotechnology Law apart from other initiatives from EU and few others countries.
The paper recommends that liability regime is require at both domestic and internation level within the exsiting environmental and redress treaties with specific focus on modern biotechnology. Several developing countries including India would have to make major legislative efforts to workout the nuances for such a regime.

Keywords: Liability; Cartagena Biosafety Protocol; Developing Countries, International Trade.

Background

Presently, there is no established international liability regime for Genetically Modified (GM) crops and hence there exists the major challenge of linking GMOs to liability and redress issues. The release of GMOs into the environment raises questions of liability and redress in both public and private law realms arising from the uncertainties. Traditionally, the discussion of legal responsibility, duty and obligation has focused on the potential environmental damage associated with GMO release.

The entry into force of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity (Biosafety Protocol) has signalled the start of a process that should lead to the development of international rules on liability and redress. The mandate for this is found in Article 27 of the Protocol which provides that:

> ...the Conference of the Parties serving as the meeting of the Parties to this Protocol shall, at its first meeting, adopt a

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> process with respect to the appropriate elaboration of international rules and procedures in the field of liability and redress for damage resulting from transboundary movements of living modified organisms, analysing and taking due account of the ongoing processes in international law on these matters, and shall endeavour to complete this process within four years.[1]

The first Conference of the Parties serving as the Meeting of the Parties (COP/MOP) that took place in 2004 adopted a specific decision on liability, formally acknowledging that the elaboration of a liability and redress regime is 'crucial for the effective implementation of the Protocol'.[2] As a result, the first COP/MOP formally started the process leading to the adoption of a liability and redress regime by setting up an Open-Ended Ad Hoc Working Group of Legal and Technical Experts on Liability and Redress.

The development of a liability and redress regime under Article 27 of the Biosafety Protocol follows a series of other sectoral environmental liability regimes that have been adopted over the past two decades. This implies that the development of a legal regime concerning genetically modified organisms (GMOs) is not conceived in a vacuum but benefits from the experience accumulated with existing legal frameworks. In fact, a number of basic legal concepts have been previously discussed in other fora and the liability and redress regime under the Biosafety Protocol should be able to largely draw from the existing legal regimes.

Similarities notwithstanding, the development of a liability and redress regime for GMOs raises a number of questions that need to be addressed separately. This is linked to the fact that the introduction of GMOs into the environment raises novel issues which have not necessarily been examined in the context of previous negotiations over environmental liability regimes. Thus, one of the main operative principles of the Biosafety Protocol is the precautionary principle and this principle influences the whole legal regime to put in place something which needs to be reflected in the liability and redress regime. Further, what constitutes damage arising as a result of the introduction of GMOs into the environment cannot be limited to definitions usually adopted till now. Some of the novel elements that need to be incorporated include the question of socio-economic damage and patent liability.

At the domestic level, the development of a liability regime is influenced by several factors. First, the existing legal regime exhibits the same limitations as the international law regime insofar as it does not include any biotechnology-specific liability regime. Second, the adoption of a liability and redress regime at the international level necessitates the adoption of a related liability and redress regime at the national level since the rules adopted under the Biosafety Protocol will not address all relevant domestic situations. Third, the existing compensation and liability regime is insufficient to deal with some of the specificities of genetically modified organisms.

Existing Liability Regimes

There is at present no international liability framework directly applicable to biotechnology. Nevertheless, the types of issues surfacing in the context of biotechnology are not completely new and states have previously developed a number of responses at the national and international levels to address the consequences of harm arising as a result of legal or illegal activities.

States have in recent times adopted a number of civil liability regimes which seek to harmonise rules concerning liability and redress. A number of treaties introducing specific liability regimes have been adopted in the case of hazardous activities such as hazardous waste disposal, nuclear energy and oil pollution damage.[3] Despite the variety of fora in which these treaties have been negotiated, they tend to provide broadly similar schemes. First, they usually adopt the principle of strict liability in recognition of the need to channel liability to the promoter or operator of the dangerous activity. This is accompanied by certain exclusions such as war or acts of god. In certain cases, the strict liability framework is supplemented by a fault-based liability for individuals that cause the damage through negligence or premeditation. Some treaties provide a possibility for the entity to which the liability is channelled to have recourse against other actors, while some deny this option to the operator such as in the case of nuclear energy. Liability is also nearly always limited in time even though this limit can extend to several decades. The amount that can be obtained is also nearly always finite. In some cases, such as in the case of nuclear energy treaties, the civil liability regime includes compulsory insurance for nuclear operators as well as a subsidiary liability of the state. In other cases such as the case of oil pollution, a scheme of strict liability can be strengthened with the introduction of an additional fund financed by a levy on oil importers. With regard to the damages taken into account damage to the environment has usually been estimated account through the consideration of damages to persons and property as well as economic interests. There has, however, been a move towards the inclusion of other elements, such as the costs of preventive measures and the costs of restoration of a degraded environment. However, even newer treaties do not usually take into account compensation for non-economic components of the environment where measures to restore the environment cannot be taken.

Besides existing international civil liability regimes, the Council of Europe has made a significant contribution by adopting a convention devoted to liability and environmental damage in general (Lugano Convention).[4] While the Lugano Convention is only a regional instrument, it has some noteworthy features that could be taken into account in the development of a liability regime for modern biotechnology. Its overall objective is to ensure adequate compensation for damage resulting from activities dangerous to the environment. Among its interesting features, the Lugano Convention recognises among dangerous activities the production, culturing, handling, storage, use, destruction, disposal, release or any other operation dealing with GMOs 'which as a result of the properties of the organism, the genetic modification and the conditions under which the operation is exercised, pose a significant risk for man, the environment or property'.[5] The Lugano Convention is also noteworthy with regard to the definition of damage it proposes which includes not only impairment of the environment – limited to the costs of measures of reinstatement actually to be undertaken – but also the costs of preventive measures and any loss or damage caused by preventive measures.

Existing Biotechnology-related Liability Regimes

The liability and redress regime under the Biosafety Protocol is likely to borrow from existing international environmental liability regimes. Nevertheless, since there is little in existing international frameworks which is directly relevant in the case of modern biotechnology, further insights on the possible shape of an international and a domestic liability and redress regime can be gained by examining some of the existing biotechnology-specific liability regimes.

At present there exist some regional instruments which can provide appropriate pointers for the development of an international regime in the context of the Biosafety Protocol and some national laws that can be referred to in the context of the development of a regime at the national level. This section considers the Organisation of African Unity's Model Law on Safety in Biotechnology which contains a section on liability as well as Switzerland's Gene Technology Act liability regime which constitutes one of the most evolved regimes in this area so far.

The liability and redress regimes to be adopted under the Biosafety Protocol and in India are likely to be different from either the African Model Law or the Swiss Act. Nevertheless, both are relevant because they address issues that must also be considered and because the development of liability regimes at the national and international levels must be considered together.

The African Model Law on Safety in Biotechnology

African countries have been in favour of the development of a stringent liability and redress regime dating from the period of negotiations for the adoption of the Biosafety Protocol. As part of the process leading to the operationalisation of the Protocol, African states adopted in 2001 a Model Law on Safety in Biotechnology which includes an Article 14 specifically addressing issues of liability and redress.

The Model Law imposes strict liability for any harm caused by GMOs or GMO products that are imported, made, in contained use, released or placed on the market. Such harm must be fully compensated. Under Article 14, liability is attached to the person responsible for the activity which results in the damage as well as to the provider, supplier or developer of the GMO. In situations where there is more than one person responsible for the damage, injury or loss, liability is joint and several.

With regard to environmental damage, Article 14 largely follows the model proposed by the Lugano Convention and provides that compensation must include the costs of reinstatement of the environment, rehabilitation or clean-up measures which are actually being incurred and, where applicable, the costs of preventive measures.

One of the important contributions of the Model Law is with regard to socio-economic aspects. It specifically provides that liability extends to harm or damage caused directly or indirectly to the economy or social or cultural practices or the livelihood or indigenous knowledge systems or technologies of a community. Such harm includes the following: disruption or damage to agricultural systems, reduction in yields and damage to the economy of an area or community.

The liability provisions are linked to a system of criminal sanctions in a range of situations outlined in Article 15. This includes cases where GMOs are imported, released or placed on the market without the written approval of the competent authority, where conditions attached to the grant of approval are violated, where false, misleading or deceptive information is provided in order to secure an approval, where GMOs are not labelled or identified or where identification is misleading or deceptive. The consequences applied under Article 15 include the usual sanction of imprisonment and fine as well as the prohibition of engaging in any activity related to GMOs for any natural or legal person that is convicted of infringement.

Overall, the African Model Law clearly reflects African states' negotiating positions during the Biosafety Protocol negotiations and their stated desire to introduce stringent liability and redress regimes as an integral part of the operationalisation of the Protocol.[6]

The Swiss Gene Technology Law

Switzerland is one of relatively few countries to have gone through a comprehensive legislative debate over genetic engineering and has adopted a biosafety legislation with a liability regime. The regime adopted offers a number of interesting lessons for the development of national and international liability regimes. This is due to the fact that while Switzerland has often adopted progressive environmental policies over the past few decades, its policies in the field of biotechnology are also strongly influenced by the important biotechnology industry lobby. Consequently, given the prevailing culture of consensus, the resulting legislation is a compromise which is generally acceptable to all actors, including the biotechnology industry and NGOs opposed to modern biotechnology.

The Gene Technology Law is a general biosafety law that has as its main aim the protection of humans, animals and the environment from abuses of gene technology and to serve the welfare of humans, animals and the environment in the application of gene technology.[7] Particularly important is that the law is based on the precautionary and the polluter-pays principles.

The liability regime adopted as part of the law is a central component of the overall biosafety regime adopted. This is related to the fact that the legislation is in part the result of a compromise whereby Switzerland would not enforce a moratorium on GMOs but would provide a legal framework providing strict conditions for the release of GMOs and a strong liability regime.

The central characteristic of the liability regime is the adoption of a strict liability framework where the injured party is a consumer or farmer. Thus, the Law provides that

> ...the person subject to authorisation is solely liable for damage that occurs to agricultural or forestry enterprises or to consumers of products of these enterprises through the permitted marketing of genetically modified organisms, that is a result of the modification of the genetic material.[8]

In other cases, there is a product liability regime whereby the person who has been given the authorisation to introduce GMOs into the environment is liable for defects which, according to the state of knowledge and technology at the time when the organism was marketed, could not have been recognised. One exception is that the person subject to authorisation can take action against persons who have handled organisms inappropriately or have otherwise contributed to the occurrence or exacerbation of the damage.

The legislation also specifically provides a duty to compensate environmental harm. It provides that the person who is liable for the use of the GMOs must also reimburse the costs of necessary and appropriate measures that are taken to repair destroyed or damaged components of the environment, or to replace them with components of equal value.

Another noteworthy feature concerns the time limit for bringing up claims against the person subject to authorisation. It recognises that it is currently impossible to determine with precision the point at which damages will occur. As a result, the law provides that the right to claim damages expires thirty years after the event causing the damage or thirty years after the date on which the GMO was marketed.

The law also addresses the question of damages to areas which are not the object of real property rights, such as common lands. It provides that where the person liable to restore or repair the environment does not take appropriate measures, the relevant community is statutorily given the right to seek reparation. This constitutes one question, which must be addressed at the international level concerning areas that do not fall under national sovereignty. The direct or indirect introduction of GMOs in the high seas is, for instance, an issue which needs to be addressed on the basis of the precautionary principle even if existing GMOs are not deemed to constitute significant threats to the high seas at present.

With regard to procedural aspects, the law specifically addresses the question of burden of proof. While it emphatically puts the onus on the party claiming damages to prove causation, it also provides that the judge can be satisfied with an 'overwhelming probability' where the proof cannot be provided with certainty.

Besides the liability regime itself, the law provides that the central government can also provide that parties wishing to commercialise GMOs may have to provide financial guarantees to cover their potential liability.

Other National Agreements

The Nigerian Guidelines impose strict liability for any harm, injury or loss caused directly or indirectly by GMOs and it is specified that the harm encompass personal injury, damage to property and financial loss. The German Act (amended in June 19, 2004) covers broad areas of private damage and liability. It includes damage to health and property and the recent amendment includes detailed heads of financial damage. Three scenarios were outlined for possible compensation: one, contamination leading to a crop being prevented from entering the market; two, contamination inducing a genetically modified labeling requirement and three, contamination destroying an *organic* distinction. Other nations like China and New Zealand have provided for private liability regimes through GMO application/registration regulations. The reach of these regimes is limited because the country's application or registration procedures need to be violated to hold a person liable.

However, Chinese regulations are distinct from others and include economic loss as one of the items for claiming compensation. The Chinese regulation is unique because it contains a damage threshold and provides redress only for those damages that cause *great economic loss*. Unfortunately the threshold quantifier of *great* is not defined (Chinese Agricultural Regulation Chapter 6 Principle 32(4), Chinese Genetic Regulation).

In the US, regulation of biotechnology products is primarily shared between three federal agencies: the Food and Drug Administration, the US Department of Agriculture and the Environmental Protection Agency. Relying on the existing laws, the agencies establish requirements pertaining to the production and use of such products, and allocate liability for the failure to comply with these requirements specified by the agencies. The US has not established any federal measures or agreements specifically tailored to address whether compensation would be available for environmental damage resulting from transboundary movements of GMOs. The damage is addressed under the existing federal legal regimes and/or the state legal system.

Specificity of Liability for Genetically Modified Organisms

The introduction of GMOs into the environment triggers a number of difficult legal questions. This is due to the fact that GMOs are substantially different from many other products insofar as they have the potential to actively interact with wild organisms once they are introduced into the environment. This explains in part the relatively strict conditions that a number of countries have put in place to regulate the introduction of GMOs into the environment so as to prevent the occurrence of harm. Nevertheless, given that the technology remains relatively recent and that its full impacts have not been ascertained, it is impossible to exclude that significant harm will not ensue following the release of GMOs into the environment. Given that human control over the technology largely ceases after the release into the environment, there is a need to provide legal mechanisms that assign liability for harm arising as a result of the release of GMOs into the environment. This has, for instance, been demonstrated in the case of the StarLink corn recall in the United States.[9]

In this context, liability and redress constitute one legal response to harm arising from legal or illegal activities. The primary function of liability regimes is usually to provide reparation to affected parties. This often takes the form of compensation. In the case of environmental harm, this may also include the restoration of the environment. Liability and redress regimes can also fulfil other functions. They can, for instance, have a preventive function to induce operators to adopt measures to minimise the risks of damage so as to reduce their exposure to financial liabilities. In this sense, liability regimes contribute to the implementation of the polluter-pays principle by imposing the integration of environmental and social costs. Liability rules can also act as an incentive to promote implementation of the existing environmental rules. Liability regimes thus provide a mechanism which can be used not only for compensation of damage having already occurred but can also contribute to damage prevention.

Three main elements need to be taken into account in the context of the development of a liability and redress regime for GMOs. The first element is environmental damage which is central in the Biosafety Protocol given that it is an environmental law treaty. In this context, significant assistance can be derived from existing liability and redress regimes but a number of issues nevertheless need to be considered in the specific context of biotechnology.

Second, as recognised in Article 26 of the Protocol, socio-economic aspects also constitute an important concern of Member states and in fact some of the main impacts of the introduction of GMOs in agriculture may turn out to be the socio-economic aspects related to livelihood concerns. These impacts need to be addressed in the context of a comprehensive liability and redress regime which contributes to strengthening of the regulatory framework for biotechnology generally. Similarly, risks to human health which also fall within the scope of the Biosafety Protocol need to be taken into account since a number of GMOs end up directly or indirectly in the food chain.

Third, another element which needs to be examined by state parties is the question of patent liability, a novel element in the context of what is primarily conceived as an environment-related liability regime. Patent liability is relevant in the context of the debate for two broad reasons. First, while there is no recognised legal connection between the granting of a patent on a GMO and the biosafety procedures leading to its commercialisation, the link exists in practice and needs to be recognised. Second, while the liability of persons illegally using a patented invention has generally been separate from biosafety considerations, this is, for instance, not the case in the context of genetically modified seeds where there is a potential clash of liabilities between the liability of the entity commercialising the seed and the liability of the farmers found in possession of genetically modified seeds without having purchased it from a licensed dealer.

Towards Liability Regimes for Genetically Modified Organisms

Modern biotechnology is a technology that has the potential for undesirable impacts even if it is implemented according to the biosafety standards that a number of countries, including India, have adopted. The simple fact that some or all of these risks may be realised is sufficient to warrant the development of a liability and redress regime. This is true at the national level for all countries which do not have liability regimes which can cover the specificities of modern biotechnology. This is also true of international law which does not include a liability regime that could cover the kinds of risks arising in the context of the release of GMOs into the environment.

Liability and Redress: An Integral Part of the Biosafety Regulatory Framework

The development of liability rules is a necessary complement to the development of biosafety frameworks. This is already implied in Article 27 of the Protocol which acknowledges that the task was left unfinished during the negotiations for the Protocol. The special characteristics of modern biotechnology reinforce the need for a separate statutory liability scheme. Relying on existing mechanisms such as torts in common law countries or existing principles of international law is an inadequate legal strategy because it creates significant uncertainty of outcomes in view of biotechnology's specificities. This will therefore neither allow the orderly development of the biotechnology industry nor provide an adequate level of protection to the environment and human health.

The Biosafety Protocol which provides the main regulatory framework for modern biotechnology seeks to balance the recognition of the potentially dangerous nature of GMOs, by providing the possibility to base decisions on the precautionary principle, and the promotion of transboundary movements of GMOs. This approach requires the adoption of a liability regime to complement a system which does not ban the transboundary movement of GMOs but recognises the potential for harm. This liability regime should be related to the primary instrument and reflect the main objective of the Biosafety Protocol which is to ensure an adequate level of protection concerning the transfer, handling and use of GMOs. This provides a way to ensure that the precautionary principle is implemented throughout the regulatory regime put in place, from the risk assessment to the liability regime and the sanctions imposed.

At this juncture, it is not possible to do more than outline a few elements that would be required to ensure the adoption of a liability regime that contributes to realising the operative principles of the Biosafety Protocol and of the existing biosafety regulatory instruments at the domestic level. First, the liability and redress regime adopted needs to have clearly defined aims related to underlying instruments. These include the need to foster environmental conservation together with the need to protect human health. More specifically, liability rules need to contribute to conserving biodiversity, soil fertility and the integrity of living organisms.

Second, liability rules need to have socio-economic objectives, including the realisation of the right to food and generally of fostering access to food as a basic need. As recognised by the African Model Law, the introduction of GMOs can have disruptive impacts on the local economy of a community which may have direct repercussions on food security where agriculture is mainly a livelihood activity.[10] Beyond the issue of basic needs, liability rules should also contribute to ensuring consumer choice between organic – and generally non-GM products – and GM products. In environmental protection terms, the development of liability rules has direct connections with the issue of co-existence of GM and non-GM crops. Without taking measures to ensure the complete separation of GM and non-GM crops, consumer choice will simply be denied in practice. Consumer choice is in fact an issue which has been given increasing recognition. Thus, in the context of the UNECE Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters (Århus Convention), the Convention's core issues have been further debated concerning GMOs following its entry into force.[11] This resulted in the adoption of a set of Guidelines on GMOs by the first Meeting of the Parties to the Århus Convention. These Guidelines provide relatively general, yet GMO specific, guidance to states concerning public participation in decision-making regarding certain GMO-related activities, access to information, its collection and dissemination as well as access to justice.[12] These Guidelines constitute an important first step in strengthening the tools available to consumers, farmers and citizens to ensure transparency in GMO-related decisions.

A number of issues also arise with regard to the choice of elements from existing civil liability regimes. Concerning the level of protection necessary in the context of modern biotechnology, the central role of the precautionary principle in the regulation of biotechnology necessitates the adoption of a strict liability approach. This is linked both to current uncertainties concerning the magnitude of possible damages and the extent to which they may occur over a long period of time. This is, for instance, the position adopted by Brazil and Switzerland.[13]

With regard to damages, the liability and redress regime needs to build upon existing principles in the field of civil liability and take into account the specificities of modern biotechnology. This implies providing a definition of damages which includes damages to the environment, to human health, to property and to economic interests. Further, the definition of damages needs to determine whether plaintiffs must wait for actual damage to become visible or whether an evidence of gene introgression is sufficient. Another difficulty which needs to be addressed concerns the different levels of risk involved with damages in different regions. Because of the nature of GMOs, the introduction of a genetically modified variety in an area which is a centre for diversity for the crop in question is of much higher significance in terms of biodiversity conservation than its introduction in another region. The liability and redress regime, therefore, needs to include special rules concerning the contamination of centres of origin given their importance in meeting today's and tomorrow's food needs for the whole of humankind. This may imply adopting an even stricter regime for zones that are either known to be ecologically sensitive or known to be of great importance for biodiversity conservation.

Another issue which needs to be determined in the liability regime is an identification of the natural/legal person responsible for the damages that may occur. Given the ability for GMOs to actively interact with wild organisms once introduced into the environment, the liability regime needs to address this issue in clear terms. The liability regime needs to ensure that a lack of specificity in liability rules does not indirectly lead to final users such as farmers being held responsible. This is an inappropriate solution given that farmers are generally unable to distinguish GM crops from non-GM crops. As a result, the solution adopted in the Swiss Law which targets the person/entity receiving the authorisation from the state to introduce a specific GMO into the environment provides an appropriate starting point. This has the advantage of making the identification of the person/entity liable relatively easier since, in an increasing number of cases, commercialised GMOs are protected by patent rights. Further, the absence of a rule focusing the liability on the patent-holder may render GMOs unattractive to farmers who might see themselves as liable to being sued by their neighbours for contamination of their fields.[14]

Patent Liability and Environmental Liability

Patent liability does not directly fall within the scope of Article 27 of the Biosafety Protocol, largely because the Protocol does not deal with intellectual property rights issues. Similarly, patent laws and treaties do not address biosafety concerns because the patent regime is in general conceived as fulfilling a different function. Nevertheless, there are increasing links between the two fields which need to be taken into account at different points in the regulatory framework. In terms of liability, the central issue is that there are different 'liabilities' for different actors that may be triggered in the context of a single event. These liabilities may be complementary or may be opposed. This is why a comprehensive liability regime for modern biotechnology needs to consider all dimensions of the issue.

The question of the respective liabilities of the company commercialising GMOs for environmental contamination and the liability of farmers who are found in possession of GM seeds without having purchased them from a licensed dealer is best illustrated in a judgment of the Canadian Supreme Court in *Monsanto Canada Inc. v Schmeiser* which provides an appropriate basis for discussing these issues at the national and international levels.[15]

This judgment raises a number of questions which are not explored here from the point of view of patent law. Besides patent issues, the judgment raises broader questions since it fails to address other important issues related to the introduction of genetically modified seeds into the environment. Thus, it does not consider questions related to biosafety, or questions related to the environmental liability of the company commercialising the genetically modified seeds, or questions related to farmers' rights or privileges.

With regard to biosafety, an important dimension of the case not addressed so far by judges is the relationship between patent liability and environmental liability. While patent protection is one of the main legal incentives for the development of modern biotechnology in the private sector, biosafety regulations are the main instrument through which environmental and health impacts of GMOs are examined. One of the main reasons why biosafety should be considered in such a case like this is that it brings up different but complementary aspects to the dispute. The patent dispute looked exclusively at the question of whether Mr Schmeiser had infringed a patent. A biosafety dispute would also have looked at the issue of whether Monsanto should be deemed responsible for introducing into the environment a genetically modified construct which has the potential to self-replicate. Seen from this broader perspective, the dispute between Mr Schmeiser and Monsanto becomes a question of the respective liability of Mr Schmeiser concerning the patent infringement versus Monsanto's liability for the contamination of his property. This raises problems which were not addressed by the court.

First, there is a need for clarity concerning the responsibility of different entities and individuals involved in the introduction of genetically modified seeds into the environment. As noted above, an appropriate solution is to provide that the entity which has been given the authorisation to introduce a GMO into the environment is solely liable for damage that is a result of the modification of genetic material. Should a different solution prevail, the legal framework should at least clearly demarcate the responsibility of the entity marketing the genetically modified organism and the responsibility of other users. In *Monsanto v Schmeiser* where the farmer is deemed to have infringed the patent even if his fields were in fact contaminated, this would seem to absolve the entity marketing the seeds from any liability and shift the burden to users. On the basis of the Schmeiser decision, the principle established would appear to be that the only legal relationship that farmers have with Monsanto is with regard to patent protection. In a situation where their fields are contaminated, they would only be able to sue their neighbours for the contamination.

Second, the issue of a balance of liabilities raises the question of the control that farmers have or can have over the land they own or use. Different farmers may take different decisions concerning the kind of agriculture they want to undertake and some decide to pursue organic agriculture. Since the definition of organic agriculture implies that there should be no genetically modified plants, contamination by genetically modified seeds would immediately disqualify organic farmers from selling their crops as organic and would lead to a loss of earnings since organic products in general fetch a higher price than non-organic ones. Unless there is a clear decision to forego organic or conventional agriculture, contamination of crops should be compensated by the entity causing the contamination. The entity which benefits from the commercialisation of the genetically modified seed should be the one shouldering the costs related to the contamination of the environment.

Third, this also raises the issue of farmers' rights. The situation can be divided between the rights of farmers who purchase genetically modified seeds and other farmers. In the case of farmers who purchase, for instance, Roundup Ready Canola from Monsanto, they have to sign a technology-use agreement which contractually restricts the rights they have over the seeds they purchase. These agreements have, for instance, been challenged in some cases in the United States but the courts have found that even if they deprive farmers of some statutory rights this does not invalidate the contract which they voluntarily sign as part of the purchase agreement with the company.[16] While the situation of farmers who are bound by a technology-use agreement seems clear at least in North America, these contractual provisions should not, in principle, affect the rights of other farmers. Farmers who do not purchase these seeds should have the rights they customarily enjoy as part of the 'farmer privilege' enjoyed under the plant breeders' rights system. These farmers should theoretically have the right to save and use seeds that they have grown even if they have been pollinated by genetically modified pollen. *Monsanto v Schmeiser*, however, seems to indicate that unless a farmer had no inkling of the potential presence of genetically modified seeds, s/he would be liable. In practice, this means that the onus of the proof is on farmers. This also implies that if farmers grow non-genetically modified crops in an area where genetically modified crops are grown, there could be a presumption that they 'ought to know' of the possible presence of protected genetically modified seeds on their fields.

Overall, *Monsanto v Schmeiser* is an important decision. On the one hand, it acts as a clear warning to other farmers that they have to watch their fields for the presence of genetically modified seeds. It also indicates that patent protection seems to prevail today over the rights that landowners have and that issues concerning biosafety, co-existence and liability are of low importance. On the other hand, the finding that the patent-holder company can in principle assert its rights on all transgenic seeds used in a commercial context whatever their origin may make the link between environmental contamination and the patent-holder easier to establish.

Policy Options

A liability regime seeks to promote the effectiveness of the underlying legal regime. The adoption of a liability and redress regime does not indicate a desire to foreclose the development of a new technology but rather to promote it while ensuring that all eventualities are taken care of. In the case of technologies whose harmful capacity has been established, preventive measures require the adoption of strong liability regimes. The same is true for modern biotechnology on the basis of the precautionary principle which provides the legal basis for addressing the uncertainties linked to this still relatively novel technology.

The development of a liability and redress regime for modern biotechnology can be linked in part to existing environmental liability and redress treaties developed over the past couple of decades since a number of basic issues are similar. Further work needs to be carried out in certain areas that have not been adequately covered earlier or that are specific to modern biotechnology. These include the question of socio-economic damage and the necessity to address the potential clash between the environmental, health and socio-economic liability of the entity introducing GMOs into the environment and the patent liability linked to the fact that most GMOs introduced on the market are protected by patents or other intellectual property rights.

A liability regime needs to be introduced at the domestic level as well as at the international level. Since it is in general not possible to 'recall' a genetically modified organism introduced into the environment, measures taken only at the national level or the international level will be insufficient to guarantee compliance with biosafety norms and principles. International law includes a number of liability regimes which can be used as a model for the development of a biotechnology-related liability regime. Domestic law is less developed in this area. Two options can be proposed to remedy this situation. Either a major legislative effort is undertaken to develop an India-specific liability regime or a regime based on existing laws such as Switzerland's gene technology act need to be introduced to ensure that existing regulatory gaps are filled.

Endnotes

[1] Article 27, Cartagena Protocol on Biosafety to the Convention on Biological Diversity, Montreal, 20 January 2000, 39 Int'l Leg. Mat. 1027 (2000) [hereafter Biosafety Protocol].

[2] Preamble, Decision BS-I/8, Establishment of an Open-Ended Ad Hoc Working Group of Legal and Technical Experts on Liability and Redress in the Context of the Protocol, in *Report of the First Meeting of the Conference of the Parties Serving as the Meeting of the Parties to the Cartagena Protocol on Biosafety*, UN Doc. UNEP/CBD/BS/COP-MOP/1/15 (2004).

[3] *See for example*, Protocol on Liability and Compensation for Damage resulting from Transboundary Movements of Hazardous Wastes and their Disposal, Basel, 10 December 1999, UN doc. UNEP/CHW.5/29, Annex III (1999), Convention on Civil Liability for Nuclear Damage, Vienna, 21 May 1963 as amended by the Protocol of 12 September 1997 and International Convention on the Establishment of an International Fund for Compensation for Oil Pollution Damage, London, 27 November 1992.

[4] Convention on Civil Liability for Damage Resulting from Activities Dangerous to the Environment, Lugano, 21 June 1993, 32 Int'l Leg. Mat. 1228 (1993).

[5] Article 2(1) of the Lugano Convention, supra note 4.

[6] Kameri-Mbote, P. (2004).

[7] Article 1, Law relating to Non-human Gene Technology, 21 March 2003, Recueil systématique 814.91.

[8] *Id.* at Article 30(2).

[9] Bratspies, R. M. (2003).

[10] See Article 14(5), African Model Law on Safety in Biotechnology (2001).

[11] Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters, Århus, 25 June 1998, 38 Int'l Leg. Mat. 517 (1999).

[12] Guidelines on Access to Information, Public Participation and Access to Justice with Respect to Genetically Modified Organisms, UN Doc. MP.PP/2003/3-KIEV.CONF/2003/INF/7 (2003).

[13] *See*, Brazil: Article 20, Law No. 11.105 of 24 March 2005.

[14] *Cf.* Section 36(a), Germany: Gesetz zum Neuordnung des Gentechnikrechts, 2004. See also Canadian Institute for Environmental Law and Policy, GMO Statutory Liability Regimes: An International Review (Toronto: CIELAP, 2004).

[15] *Monsanto Canada Inc. v Schmeiser*, Supreme Court of Canada, Judgment of 21 May 2004, 2004 SCC 34.

[16] *Monsanto v McFarling*, United States Court of Appeals – Federal Circuit, 23 August 2002, 302 F.3d 1291.

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Biosafety and Emerging Socio Economic Issues

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Abstract: India, as a party to the Convention on Biodiversity and having ratified the Cartagena Protocol (CP) is committed to the safe handling of living or genetically modified organisms (LMOs or GMOs). CP provides a broad framework on biosafety especially focusing on transboundary movements of GMOs and also covers seeds that are meant for intentional release in the environment, as well as those GMOs that are intended for food, feed or used in food processing. A number of countries have drafted their biosafety regulatory framework taking into consideration the socio-economic aspects of release of GMOs, the common feature emphasised being the health and economic loss due to the release of such GMOs. Besides many countries have also emphasised the labeling requirements to enable consumers to make a choice. In the case of India, the regulatory framework, does not adequately emphasise the socio economic aspects, the need for which has been realised after the release of GMO; in the environment. To examine the implications more research is going on in both public and private sector in India. The major lacuna in the Indian system of adoption of GMO was, the failure of the monitoring of the GM crop after the commercial release to ensure proper implementation of biosafety measures. Failure to adopt bio safety measures, irrational use of pesticides and an indiscriminate crossing of the unapproved variety could lead to wide spread pest resistance and resurgence and leading to a potential technology not utilised optimally.

Keywords: Biosafety, Labeling, GMOs.

Introduction

Biosafety can be broadly defined as the safety concern regarding damages to human, environment and other living beings due to intentional or unintentional, authorised or unauthorised experiment

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or use of technology. These concerns surface in view of the opening up of agriculture for international trade through which trading of Living Modified Organisms (LMOs) or Genetically Modified Organisms (GMO) could take place. India is party to the Convention on Biodiversity and has signed and ratified the Cartagena Protocol on Biosafety (CPB) in January 2001 and is therefore committed to the safe handling of GMOs. The CPB provides a broad framework on biosafety, exclusively focussing on the transboundary movements of LMOs. The Indian biosafety policy as of now focuses on zealously detailed scientific considerations about the various testing procedures of GMOs prior to the open environment release/in-house research and testing (Department of Biotechnology available at http://www.dbtindia.nic.in/thanks/biosafetymain.html). A meticulously set up regulatory framework is in charge of implementing the biosafety regulations in the country.

Considering the research on a number of genetically modified food and other commercial crops undertaken both in the public and private sector in India, it is essential that the biosafety policy of India be 'reshaped' focusing on the socio economic aspects along with scientific aspects. Since a sizeable population in India is dependent on agriculture, which is linked to the monsoon and availability of appropriate material inputs, including seeds, the farmers would try any new technology introduced to improve the yield and returns as it happened during the green revolution days. However, the adverse impact of the green revolution namely, mono-cropping, loss of local cultivars or land races, imbalances in soil nutrients and excessive use of fertilisers and pesticides, have affected the soil productivity and the returns to agriculture. The damage caused has gone beyond repair in certain regions. Crop failures due to poor quality seeds or ineffective pesticide sprays on the pest are common which have led to farmers committing suicide in certain places of the country. However, there are limited cases in which the person/company responsible for the failure was legally tried and was made to pay compensation. Therefore, when India opened up the agriculture sector for international trade, many genetically modified organisms could enter the country either in the form of food or materials that can be used as a source of production. In this brief write up, we draw a socio-economic framework that may be taken into consideration when the government is considering the open release of GMOs as a source material for cultivation.

Socio-Economic Framework of Biosafety

The labeling requirement designed and adopted by different countries can be considered as a first step taken by the countries in the social framework of biosafety. Such labeling requirement gives the ethical right to the consumers to know and decide whether they should consume materials containing GMOs. The labeling requirement arises from the fact that there is a possibility of harm from GMOs, which could be categorised as serious irreversible harm, avoidable harm and likely harm *(to humans and environment).* Hence countries resort to monitoring, labeling, bans, phase-outs, pre-marketing testing, setting goals *and standards for* degree of protection, reduction of hazard, prevention of and contamination of GM with non GM material, etc. The degree of protection adopted by different countries is presented in Table 1. Basically, this table outlines the global initiatives of different countries regarding labeling of GM crops and food. The EU requires mandatory labeling and has a threshold tolerance level of 1 per cent (majority of EU members comply with the EU standards) (EU Directive on Food Safety available at http://europa.eu.int/comm/food/fs/ifsi/eupositions/tffbt/tfbt_ec-comments_cl0127_en.pdf and European Legislation on GMO's, available athttp://gmotraining.jrc.it/docs/Session01.pdf). In the United States labeling is voluntary. Most Asian countries have signed and ratified the Biosafety Protocol, but do not have any specific regime on labeling. A majority of African countries on the other hand are still developing their biosafety regulatory framework and have banned GM food until the passing of the biosafety legislation. In this context it may be worth mentioning that Swaziland, Lesotho and Mozambique accepted GM food but Zambia, Malawi and Zimbabwe were reluctant to receive GM food aid from USA. These governments refused the food aid on the grounds of possible health and environmental effects. Another issue of concern is that of contamination of crops. Eventually under international pressure, USA sent 30,000 tons of non-GM food aid to that region (Clapp,2006).

Australia and New Zealand have identical labeling requirements for food with greater than 1 per cent GM ingredients (Baumeller, 2004, *Report of the Royal Commission on Genetic Modification*, 2002). One implication that emerges from this Table is that the labeling condition is perhaps related with the level of development of the country.

As far as India is concerned, though, the Indian regulatory framework is process based whereby the process of arriving at the GMO

Table 1: Comparison of Worldwide Regulations Concerning GMOs:

Country	Labeling Requirements	Ban or Moratorium on Commercialization	Ban on Imports
AFRICA			
Algeria		Dec 2000: Ministerial Order prohibits the import, distribution, commercialization and utilization of GM plant material	Dec 2000: Ministerial order prohibits the import, distribution and utilization of GM plant material
Benin		April 2002: 5 year moratorium on import, commercialization and use of GMOs and their products	April 2002: 5 year moratorium on import, commercialization and use of GMOs and their products
Sudan			May 2003: The govt issued a memorandum that food aid be GM-free; under pressure from USAID,the memorandum waiver has been extended until June 2005
Zimbabwe			May 2002: Govt rejected GM food aid.No GMOs are currently allowed into the country except milled maize
ASIA			
China	Jan 2002: Decree No 10 of the ministry of Agriculture. www.agri.gov.cn(Chinese)		
Indonesia	1996 Food Law contains regulations regarding Labelings, however yet to be implemented. www.deptan.go.id/english		

Table 1 continued

Table 1 continued

Country	Labeling Requirements	Ban or Moratorium on Commercialisation	Ban on Imports
Japan	March 2003: Food Sanitation Law and Japan Agricultural Standards Law www.maff.go.jp		
Korea (South)	March 2002: Regulated by the Ministry of Agriculture & Forestry and the Korea Food and Drug Administration. www.maf.go.kr		
Saudi Arabia	Dec 2001 Saude Ministry of Commerce Decree no 1666. www.commerce.gov.sa/english (under construction)		
Taiwan	Feb 2001 : Dept of Health No 0900011746		
Thailand	2002: Public Health Ministry Announcement		
EUROPE:			
European Union	April 2004: EU requires all foods and ingredients produced from GMOs to be labeled, except adventurous levels upto 0.9% of those GMOs currently approved in the EU	Sept 8: European Commission approves the first GE seeds for purchase and planting, marking the end of a nearly 6 year de facto moratorium.	May 19 2004:EC vote to allow imports of Bt 11 maize ending the moratorium in place since 1998.

Table 1 continued

Table 1 continued

Country	Labeling Requirements	Ban or Moratorium on Commercialisation	Ban on Imports
Austria	EU Compliant	Between 1997-2000: Banned 3 varieties of GM maize using the safeguard clause in EU legislation.	Between 1997-2000: Banned 3 varieties of GM maize
France	EU Compliant	Nov 1998: France banned 2 varieties of GM rapeseed	Nov 1998: France banned 2 varieties of GM rapeseed
Georgia		April 1996: Ban on GM import and cultivation until legislation created.	April 1996: Ban on GM import and cultivation until legislation created.
Greece	EU compliant	Sept 1998: A variety of GM rapeseed banned	Sept 1998: A variety of GM rapeseed banned
Germany	EU Compliant	March 2000: Banned a variety of GM maize Jan 2005: Genetic Engineering Act came into force; does not ban cultivation outright however, makes GM farmers liable for contamination and dissuades use of GM crops.	March 2000: Banned a variety of GM maize
Hungary	EU Compliant	Jan 2005: Temporary measure banning import, production, use and distribution of MON 810 maize seeds (EU approved crop)	Jan 2005: Temporary measure banning import, production, use and distribution of MON 810 maize seeds (EU approved crop)
Italy	EU Compliant	Feb 2005: Italian Parliament replaced the 2000 ban on GM food, feed and cultivation with a co-existence law that allows each region to set its own rules. Not a ban. However, most regions have said they want to remain GE free	

Table 1 continued

Table 1 continued

Country	Labeling Requirements	Ban or Moratorium on Commercialisation	Ban on Imports
Luxembourg	EU Compliant	Feb 1997: Banned a variety of GM maize	Feb 1997: Banned a variety of GM maize
Norway	Oct 1997: Products containing GM material are labeled if the modified component contains more than 2% of the ingredient	No ban, however Norway is a member of the European Economic Agreement and is obligated to follow EU food safety standards. Despite this, Norway has the authority to reject any EU approved GMO and has done so 8 times. Currently only non-food crops (tobacco and carnations) are approved for marketing	
United Kingdom	EU Compliant	2001: EU banned the cultivation of GM sugar beet	
SOUTH AMERICA			
El Salvador	1999: National Strategy for BiologicalDiversity allows experimentalPlanting of biotech cotton but does notPermit the planting of other biotechCrops		
Mexico	April 2003: Law of Bio safety for Genetically Modified Organisms	1999:Ban on experimentation with corn Oct 2003: De Facto Moratorium on growing GE crops lifted to allow planting for experimental purposes. Feb 2004: Banned commercialisation of GE maize	Feb 2004: Ban on import of GE maize

Table 1 continued

Table 1 continued

Country	Labeling Requirements	Ban or Moratorium on Commercialisation	Ban on Imports
Brazil	2002 Labeling required for products with more than 4% GMOMarch 2004: Food products with greater than 1%GMO must be labeled, except GM Soya. It is unclear if the law apples to imported products www.mj.gov.br/sde/	2000: Ban on cultivation of GE soy 12/1/2005: Provisional measure 223 allows the planting & marketing of GE soy till 31 Jan 2006	Prohibits the entry of Gmo without prior approval
OCEANIA			
Australia	Standard 1.5.2 of the Food Standards Code states that foods greater than 1% GM ingredients must be labeled www.foodstandards.gov.au.		
New Zealand	Standard 1.5.2 of the Food Standards Code states that foods greater than 1% GM ingredients must be labeled www.foodstandards.gov.au.	No ban, however there have been no approved release applications due to strict regulations	No ban, but strict regulations have resulted in any live GMO crops or seeds approved for importation

Source: Centre for Food Safety, Washington D C., February, 2005.

level is scrutinized, the Indian biosafety law on the other hand stops with saying that we need to tread cautiously in matters concerning hazardous materials like GMOs (Department of Biotechnology). In our opinion this should be the guiding force of any GMO research or/ entry of GMOs. For transboundary shipment of goods perhaps these may be sent back if identified appropriately at the entry point itself. But once the GMO is released as in the case of India, what are the options left?

Basically to help those countries which are on the threshold of GM research and use, the Cartagena Protocol (CP) stresses the need to set up a Biosafety Clearing House. The role of BCH is to:

(a) Facilitate the exchange of scientific, technical, environmental and legal information on, and experience with, living modified organisms; and

(b) Assist parties to implement CP, taking into account the special needs of developing country parties, in particular the least developed and small island developing States among them, and countries with economies in transition as well as countries that are centres of origin and centres of genetic diversity.

The BCH is essential for the successful implementation of the CPB. For example, it provides a "one-stop shop" where users can readily access or contribute relevant biosafety-related information. This would assist governments to make informed decisions regarding the importation or release of LMOs. Information in the BCH is owned and updated by the users themselves, thus ensuring its timeliness and accuracy. By allowing easy and open access to key information, the BCH also fosters greater transparency in the implementation of the Protocol and this facilitates effective participation of the public and civil society in the decision-making process. Thus, for countries, which are still evolving an appropriate biosafety framework based on socio-economic considerations, setting up a BCH or being part of the BCH is essential. Presently, the Asia BioNet functions as the BCH of the Asian countries though it is yet to gain its official status. Asia BioNet initially started out as the official website of the Food and Agriculture Organisation-Regional Office for Asia and the Pacific (FAO-RAP) collaboration with the Government of Japan to fund Capacity Building Initiatives in the participating countries. Though the four-year project which started in May 2002 ended in April 2005, the website continues to be the depositary for GM information of all the participating countries. Participating countries in the Asia BioNet effort are: Bangladesh, China, India, Indonesia, Malaysia, Pakistan, Philippines, Sri Lanka, Thailand, Viet Nam and other selected countries in Asia and the Pacific. Such a BCH would help in providing information on export and import policies and procedures regarding GMOs.

Risk Assessments and Management

Risk assessment and management principles should be the fundamental guiding force of an appropriate socio-economic framework. In the case of GMOs that are used as source material the risks need to be spelt in detail as they will have to take care of the risks that could arise during the handling of GMOs, open release of the same and the after effect of the open release. In this context, Article 26 of CPB directs attention towards, risk assessments that would basically look at the socio-economic impacts on indigenous and local communities (Cartagena Protocol on Biosafety, available at http://www.biodiv.org/biosafety/default2.aspx). The Indian biosafety laws also echo the same. Such impacts however need to be defined. In the following paragraphs we detail some of the risk assessment frameworks that are available.

When we talk about the risk assessment and management, it is worth taking a look at the Australian regulatory framework. Though this framework, (described as the Office of the Gene Technology Regulator–OGTR), does not explicitly mention the socio-economic framework, it allows for the assessment and management of two aspects of concern: (a) risk to public health and safety of the people and environment, and (b) non-compliance with the legislation. The frequency and severity of risk to the health and safety of the public and the environmental impacts determine the type of compliance response. A non-compliant activity may by itself represent negligible risk. However, the frequency of non-compliant behavior warrants a different type of compliance strategy. As part of the compliance strategy, the promoter educates his staff and provides information to the government on the GMO activities undertaken in his organisation. Based on this the OGTR conducts spot checks. In case of non-compliance, warning letters, minor penalties, etc. are issued. If the level of non-compliance is still persistent then the intervention of the court is sought. Even after this, if non-compliance is continued then extreme measures like cancellation of license, bans, imprisonments, etc. are resorted to. The OGTR also includes corporate commitment to documentation on effective risk management and compliance practices together with corporate culture thus enabling organisations and personnel to comply (Risk Analysis Protocol and Monitoring and Compliance Protocol, OGTR, available at http://www.ogtr.gov.au/pdf/moncomp/riskanapro.pdf).

The brief outline of the system provided above points to the structure that has been created for the anticipation of risks as well as non-compliance by the promoters of GM technology. A system like the Australia system would be too ambitious for India at this juncture. However, considering the research that is currently being carried out in India both in the private and public sector and the products that could enter the country through the free trade regime, India should take initiatives to set up a similar strong risk assessment and compliance framework. India for instance, has already built in the corporate culture where by Mahyco (the company which has released a GMO in the form of Bt cotton) has been asked to monitor the bollworm infestation in the crop and to undertake studies on the possible impacts on non-target species and report the same to the government.

Presently, there is no established international liability regime for genetically modified crops and hence there exists the major challenge of linking GMOs to liability and redress issues. However, a few countries have considered the impact of GMOs on health and environment and have designed the liability regime based on that (Migues. 2004, Liability and Redress for Damage Resulting from the Transboundary movement of LMO's, 2001 available at http://www.biodiv.org/doc/meetings/bs/iccp-02/official/iccp-02-03-en.pdf). Hence to that extent this can be considered as the importance given to the socio economic aspects of biosafety.

International laws such as the European Union's Environmental Liability Directive EC, Council Directive 2004/35/CE of 21 April 2004 is not limited to trans-boundary damage alone. The EU Liability Directive covers the environmental damage caused by GMOs and is based on the *polluter pays* principle. The directive's narrow definition of environmental damage however includes damage to protected species and natural habitats, and land contamination that creates the significant risk of adversely affecting human health and the land productivity. The possible harmful effects that could occur outside the protected habitats are not covered. The directive does not confer protection for all potential damages; it is significant that it recognises the release of GMOs as a possible activity leading to environmental harm (European Union, Regulations and Directives on GMO's, 2005 available at http://binas.unido.org/binas/regulations/EUdirectives.pdf).

The Nigerian Guidelines impose strict liability for any harm, injury or loss caused directly or indirectly by GMOs and it is specified that the harm encompasses personal injury, damage to property and financial loss (Nigeria Biosafety Guidelines, 2001). The German Act 1993 (amended in June 19 2004) covers broad areas of private damage and liability (German Act, 1993). It includes damage to health and property and the recent amendment includes detailed heads of financial damage (*New Zealand Law Commission Report*, 2002). Three scenarios were outlined for possible compensation with a clear socio economic focus: one, contamination leading to a crop being prevented from entering the market (and thus could affect the economic returns earned by the farmer); two, contamination inducing a genetically modified labeling requirement (which could affect the trade prospects) and three, contamination destroying an *organic* distinction and thus may prevent organic cultivation in future.

The Chinese regulations are distinct from others and include economic loss as one of the items for claiming compensation. The Chinese regulation is unique because it contains a damage threshold and provides redress only for those damages that cause *great economic loss*. Unfortunately the threshold quantifier of *great* is not defined (Chinese Genetic Regulation, 1996).

The above discussion highlights that there are some elements of socio economic consideration in the biosafety framework of different countries. The bottom line is the damage to health and economic loss. With this background, a few observations are made in this section on the experience of open release of GMO, namely the Bt cotton, for commercial cultivation in India since 2002. These are known as the Mech 12, Mech 162 and Mech 184 cotton variety. The original Bt gene invented by Monsanto is patented in the US. This technology was licensed to MAHYCO, an Indian seed company which commercialised the above mentioned three varieties after conducting field trials for a period of three years which ended in 2005. In 2005 two more companies namely, Rasi seeds and Ankur seeds were given permission to release their varieties. The MAHYCO varieties were reviewed based on their performance and were given approval for sale for two more years. However, due to an unsatisfactory performance of the varieties in Andhra

Pradesh, the Mech 12, 162 and 184 have been withdrawn and new varieties of Mahyco have been introduced. Both the Mahyco and the Rasi seeds have been priced at around Rs.1600 for a packet of 450 grams.

The following are some of the observations based on the performance of the Bt cotton in different parts of India.

Observations from the Field

Yield Differences

Performance of the GMO released so far has not been consistent in terms of yield and economic returns, though the same varieties were released in other states. Generally the performance of Bt seeds had been better in the irrigated than in unirrigated areas. In Gujarat for instance, Mech 12 did not perform well, whereas in Andhra Pradesh Mech 162 was a failure. The farmers in any case did not get any compensation from the company though they had bought the seeds from authorized sources.

Further there are wide differences between the results obtained by studies sponsored by the company, independent researchers and NGOs as indicated in Table 2. In the absence of a uniform methodology adopted by these studies it is difficult to comment on the results. Yet from some of the independent research that has been done, it emerges that the new technology has not reduced the cost of cultivation and the yield increase reported in a few places seems to have been offset by the increase in the seed cost incurred by the consumers.

Price Impact

The price of the approved seed is relatively higher than the conventional and the hybrid seeds at Rs.1600,[1] whereas the unapproved variety is sold at half the price of the approved seeds. Both Gujarat and Andhra Pradesh states witnessed a widespread cultivation of the unofficial variety. Thus, in a way the higher price of the officially released seeds has also led to the spread of the unofficial seeds.

There are confirmed reports from almost all cotton growing parts of the country about the spread of the unofficial hybrid variety, which evidently contains the GMO. The first and foremost issue here is that, this variety cannot be recalled. This strikes a serious note in the context of unofficial and indiscriminate crossing of Bt cotton with other cotton varieties, which could develop resistance sooner than what, is expected. This needs to be looked at in the context of the declining popularity of

Table 2: Performance of Bt Cotton in Selected States

State	Reduction in Bollworm pesticide		Yield Increase		Increase in net profit	
	%	Rs.	%	Quintal per acre	%	Rs. Per acre
Andhra Pradesh	58	1856	24	1.98	92	5138
Karnataka	51	1184	31	1.36	120	2514
Maharashtra	71	1047	26	1.48	66	2388
Gujarat	70	1392	18	1.20	164	3460
MP	52	889	40	2.2	68	3876
All India Weighted average	60	1294	29	1.72	78	3126

Source: AC Neilson survey 2004.

the local varieties. It emerges from the State of Gujarat that since the release of both the official and unofficial Bt varieties, the sales of the state seed corporation, which sells conventional, and hybrid varieties, have reduced considerably which indirectly indicates the decline in popularity of the local varieties. It is not clear whether the farmers if and when they decide to cultivate the old varieties, can do so. Or would there be difference in the performance?

Refuge Compliance

One of the biosafety measures supposed to be adopted by the farmers was the cultivation of refuge, whereby 20 per cent or five rows of non-Bt cotton is supposed to be cultivated around the Bt plot which will serve as the host for the bollworms that could affect the Bt cotton. Evidence from the GIDR survey[2] and the Andhra Pradesh experience shows that not every body had complied with the refuge criterion (perhaps studies could be done on the extent of damage and resistance with and without refuge). The potential impact of all the refuge violations are not immediately visible. This is perhaps one of the reasons why the policy makers turn a blind eye or take mild action if at all.

Impact of the spread of the unofficial variety

The illegal crossing of the varieties also forewarns what kind of plant protection can be offered for any new variety that is developed in India or brought from elsewhere. It is also not clear what impact the GM cotton has had on the neighbouring field or the soil nutrients. Evidence from the field shows that soil testing is not done very frequently. A few farmers reported that they undertake soil testing on their own as they realised that their soil has turned hard after they started using GM cotton (GIDR survey). The Centre for Sustainable Agriculture's study (2005) done in Andhra Pradesh shows that (which however needs further investigation) farmers who cultivated chilli in the land that was used for Bt cotton cultivation in the earlier year got poor yields compared to others who did not cultivate Bt.

Other Issues in Bt cultivation

It is a matter of debate that had the Bt gene been introduced in the variety that is found suitable for the region then would there be difference in the results? But now for this lapse in the research, can the company be held responsible and liable to pay compensation to the farmers, or should the government be held responsible for allowing these seeds uniformly in all the regions?

Further, the question of using farm-saved seeds is an important aspect of Indian agriculture. In the case of hybrid cotton varieties, the seeds loose their vigour after one or two cultivations. In the case of GM cotton also, it is not effective after the second use, which makes the farmers depend on the market which could affect their livelihood. In the absence of appropriately defined formal credit sources, farmers fall prey to informal credit sources.

Importantly, GM cotton has also entered the food chain in the form of cottonseed oil and cattle feed. Since the labeling requirement is not followed in India, many consumers may not even be aware of this aspect. This is an ethical issue as consumers are not aware of it.

These broad observations on different aspects of Bt cultivation suggest that in the absence of appropriate data on the socio economic framework/consideration, the government can not take appropriate decision on whether a new technology of the nature of GMO can be used as a source material. Hence, in the future before any further release of GMO is undertaken the government should ascertain some of the facts based on the following indicators to educate the farmers and diffuse the technology appropriately among the main stakeholders, namely, the farmers.

- Accessibility of the technology across different land holdings. Can farmers with different size holdings access this technology? Does the technology necessitate any prior knowledge or awareness for effective use?
- Will the specific characteristics of the technology like the price of seeds or the safe adoption measures prescribed lead to exclusion of certain classes of farmers from adopting GM technology?
- Have the farmers observed any impact on health such as poisoning, nausea, skin irritation, headache, temperature etc?. What kind of pesticides do the farmers use and what are the implications of using such pesticides? Also, did they lose income or man days due to their illness?
- Whether there is any difference in the health of cattle on farms where GM is used and those that were fed the by products of cotton.
- Has adoption of GM technology resulted in increased income realisation across different size holdings or increased income disparity?

- Does the new technology lead to displacement of labour? Are there any differences in the wages given to the farm workers between the GM and non GM farms.
- Has there been any difference in the employment created in the GM farm by gender?
- Are the consumers aware of the fact that since the farmers do not segregate the GM and non-GM cotton varieties in the yard, the GM residues, if any, could have entered the food directly and through the food chain? If so, what are the likely impacts?
- Have the farmers observed any difference in the material inputs requirement in the GM and non-GM farm? In other words does the use of new technology lead to increase in yield or reduction in use of the material inputs such as pesticides, fertilisers or water requirements?
- Can the technology be used in the rain fed region also? Or does it require irrigated conditions. Alternatively will there be yield differences between the irrigated and rain fed regions?
- Since the farmers routinely use the farm saved seeds for cultivation, is it possible to use the farm saved seeds for further production? Or will it lead to increased reliance on markets?
- Can the refuge criterion be complied with? If so, what are the mechanisms of monitoring? If not what is the alternative?
- Could there be differences in the yield due to adhering or non-adhering to the refuge criterion?
- If the farmers have experienced crop failure after they adopted GM, were they compensated by the company? Were there any form of security available to them?
- Will or/has there been any difference in the market price of these two varieties? At alternate price levels what could be the adoption rate and benefits?
- Could introduction of a few uniform varieties in different regions affect the bio-diversity in that place?
- If there is a need to separate the GM and non-GM crop, what are the cost implications for the farmers and is it feasible?
- Has there been a decline in the use of other varieties that were traditionally used by the farmers after the introduction of GM cotton?
- Have the farmers observed or undertaken any soil testing measures after they adapted GM cotton?

- What would be the cost of creating awareness among the farmers and the cost of monitoring of the same for safe and sustainable use of technology?
- Will the agency diffusing technology provide all credit and material input support? How expensive is the technology o adopt. Does it require, the setting up of a specialised credit system, etc?

Some of these issues clearly drive home the message that there has to be continuous follow up of the GMO once it is released and that information flow from the field level to the higher authorities in charge of regulation should also be continuous.[3] Both these are very essential to take a rational decision on whether India needs to continue research on the entry of GMO as a source material. It is now known widely that many of the states where GM cotton was released did not have a State Biotechnology Coordination Committee and where it was set up the officials hardly knew what they were supposed to do. This highlights the urgent need for capacity building at different levels of regulatory framework and among the different stakeholders/or users of the technology.

Whenever a new seed is released by the public sector, it goes through a routine process of seed certification after the research stations of the state agricultural universities report on the said seed After this, the extension workers under the Training and Visit programme, who have adequate information about the new seeds visit and train the village-level workers. The village-level workers contact the farmers and explain the salient features of the new variety and motivate them to adapt the new variety. However, the scope of public extension workers is limited to the public sector seeds only.

The private sector has its own method in spreading information about their seeds — at the district level they have area managers and dealer networks up to the taluka level. At the village level, they have agriculture graduates or diploma holders who provide information about the seeds and the other features and the public sector is not in the picture at all. However, in the case of GM cotton in India, the technology has been introduced by the private sector, but since the technology is different the government had to intervene in terms of providing clearance and approval for diffusion of the same. The GM seeds are developed by the private sector. Therefore, the question is whether the government should leave the entire responsibility of performance evaluation from the fields to the company itself or should it intervene and collect information periodically about the performance of the variety to get correct information/remedial measures. This is because, the public extension system mainly works for the public sector seeds/programmes, it appears there is very little information about the new seed technology. On the other hand, the private company's extension service had also served a very limited purpose.

Therefore, in the interest of the larger community, it is essential that the government steps in and sets up a public private partnership. This partnership should strengthen the (a) monitoring and extension mechanism, and (b) emphasise thecapacity building aspect of those field level functionaries. Capacity building of the field level functionaries and the link between the government/company and farmer, is important so that there should be an unhindered flow of information on the salient features of the technology and the appropriate method of cultivation. This public-private partnership would not only be useful for minimising the risks in the case of GMO that has already been released, but it would also be helpful in strengthening/laying down strong principles.

The setting up of an effective regulatory regime that incorporates all these aspects could be highly resource draining at least in the initial stages but would lead to lesser risks in the future. On the other hand, if the government does not have the regulation in place, it could lead to more risks.

Perhaps in the case of agricultural GMOs like the present GM cotton in India, greater weightage should be given to strengthening the field level functionaries who could present important information on the performance, health and environmental impact of the GMO. If this could function along with an effective public-private partnership in reaching the ultimate consumers of GMO, perhaps avoidable risks like compliance with the refuge mechanism, failure of an approved variety which is the reason for farmers options for unapproved seeds, and the indiscriminate crossing of the varieties could have been prevented/minimized. More importantly, the said benefits of the approved variety, namely the reduced use of pesticides could have been experienced. As the farmers have not been properly explained the technology, the refuge criterion is not complied with and the excess use of pesticides on the cotton continues. The Indian case presents a situation where this important link with the farmer and the aspect of capacity building has been completely missed out. Capacity building of the ground level functionaries would prove to be helpful in identifying the risks if any and passing of this information to the higher authorities that can plan risk management mechanisms and also in identifying the faulted person/persons in fixing compensation.

Conclusion

The above discussion indicates that Indian biosafety measures should take the socio-economic issues into consideration. Since more yield enhancing and pest controlling GMOs could be introduced in the future, the social and economic impact that GMOs could leave on the ultimate consumers should be seriously thought of. For instance in case of failure of technology who will pay and how the compensation will be paid? In this context, a lesson or two can be learnt from the Andhra Pradesh model. Since the early 2000, companies selling seeds here have to enter into a memorandum of understanding with the state government. In the event of seed failure, such a company will be directed to pay compensation to the farmers. Mahyco was also held liable for the failure of the crop in the Warrangal region[4] where it was asked to pay a huge compensation. However, the company has gone to the court. The Indian Plant Variety Protection Act states that where any propagating material of a variety registered under this Act has been sold to a farmer or a group of farmers or any organization of farmers, the breeder of such variety shall disclose to the farmer or group of farmers or organization of farmers as the case may be the expected performance under 'given conditions'. If such propagating material fails to provide such performance under such given conditions, the farmer or group of farmers or organization of farmers may claim compensation in the prescribed manner before the authority. The authority after hearing both the parties may direct the breeder of the variety to pay compensation to the farmer or the group of farmers. However, both the Andhra Pradesh model and the plant protection route would be helpful only for those farmers who have taken seeds from authorised sources selling authorised or certified seeds. But the problem for India is that a lot of seeds are circulating. In the case of failure of these seeds who would be held responsible?

The underlying argument is that a technology such as the GMO has a high potential to benefit the developing countries if applied carefully. But inadequate knowledge and improper diffusion could lead to the improper use of technology by which the potential of the technology is lost for short-term gains. As mentioned earlier, the adverse impacts of the green revolution are emerging now which are not rectified yet. Before that we have opened the doors for another technology. Now at least in order to realise the potential impact of the technology and sustainable use of the same, adequate safety measures based on the socio-economic considerations should be set up and complied with.

Endnotes

[1] In May 2006, the Monopolies Trade Restrictive Practices Commission based on the point raised by the Government of Andhra Pradesh has imposed price control on Bt cotton seeds by which the price of a 450 gram packet has been reduced to Rs.750.

[2] Survey conducted among the cotton cultivating farmers in selected districts in Gujarat, by Gujarat Institute of Development Research in 2002 and 2004.

[3] The present regulatory framework prevailing in India indicates a top-down approach and stops at the District level Committee. Such an approach necessitates that the reverse order flow of information from the district to the central government has to be there to ensure that bio safety regulations are complied with and GMOs are monitored for their safety and performance considerations.

[4] Private communication with seed sellers in Hyderabad.

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Biotechnology, Bioethics and National Ethical Guidelines in Biomedical Research in Iran

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Abstract: Rapid advances in biotechnology and science are resulting in an ever-increasing demand for global responses to the related ethical issues. These advancements could lead to irreversible disasters if not limited by ethical guidelines. In the last decade, there has been a special attention focus on biotechnology development and bioethics empowerment in Iran. In this paper we aim to review the situation of biotechnology in Iran. The main national bioethical activities will be addressed. We also discuss the "National Ethical Guidelines of Biomedical Research", including 'genetics research' and 'gamete and embryo research' which have been compiled recently.

Keywords: Bioethics, medical ethics, biotechnology, ethical guideline, Genetics, gamete donation, embryo donation, Islam, Iran.

Introduction

Biotechnology has confronted the world with some bioethical challenges which have raised numerous questions with no definite answers. Genetic engineering, genetic manipulations, genetic testing, gene therapy (somatic cell and germ cell), eugenics, selective abortion, genetically modified foods, behavioral genetics, new Assisted Reproductive Technologies (ARTs), stem cell research and cloning are some of the most important issues. The ultimate goal is to use these technologies to

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develop new ways to treat, cure, or even prevent thousands of human diseases. However, these developments have raised ethical and societal concerns about how resulting technologies will be implemented, and about how their implementation will impact different communities. Amongst all, concerns about subjects' rights, informed consent, privacy, patenting and ownership of genetic material, development of biobanks, forensics, the commercialisation of products including property rights and accessibility of data and materials require special global attention. Consequently, many attempts have been made by scientists, ethicists, jurisprudents and lawyers for compiling international and national guidelines for the regulation of and legislation in this field in recent decades.

Iran, with a long history of science and with great scholars, scientists and philosophers, has played an influential role in world civilization. The great Iranian scientists have paid special attention to ethical insights in the scientific realm.[1] The recent International Congress of Bioethics in Iran (2005) was a major step forward in reaching an agreement on the important issue of bioethics[2] it was a step towards reaching an agreement for the final declaration of bioethics.[3] The Tehran Statement[4] clearly showed that the international community is aware of the hazards and the benefits of biotechnology, and is willing to accommodate all facilities to use this robust science in the right way and to impede any possible abuses.[5]

In this manuscript we aim to present the biotechnological situation pertaining to Iran and to address some bioethical activities in this field. Likewise, we also intend to mention the *"National Ethical Guidelines of Biomedical Research"*, including 'genetics research' and 'gamete and embryo research' which have been compiled recently.

Biotechnology in Iran

Iran is one of the pioneers of biotechnology in the Eastern Mediterranean region. In this area, the Pasteur Institute of Iran and Razi Institute both have more than 70 years' experience in conventional biotechnology. The Pasteur Institute of Iran has been acting as a national centre of infectious diseases diagnosis and vaccine production since 1920.[6] Molecular biotechnology started from the Biotechnology Department at the Pasteur Institute of Iran and the National Research Centre for Genetic Engineering and Biotechnology (NRCGEB).[7] The NRCGEB was established in 1988 under the supervision of the Ministry of Science, Research and Technology.[8] The major activity of NRCGEB in the area of medical biotechnology is concentrated on human genetic disorders, recombinant protein and heterologous gene expression. The Biotechnology Department of the Pasteur Institute of Iran (1993) was officially entitled Biotechnology Research Centre (BRC) in 1997.[9] Likewise, an organization called the Iranian Biotechnology Society (IBS) was founded in Iran in 1997 that has more than 350 members at present.

In recent decades, Iranian policymakers tried to facilitate the infrastructure movement in the area of modern biotechnology. Some important governmental bodies related to biotechnology in Iran are: the Supreme Council in Biotechnology, 2005 (under supervision of the President), the Technology Cooperation Office of the Presidency, Medical Biotechnology Committee, 1998 (the Ministry of Health and Medical Education), the National Medical Biotechnology Network, 2002 (Deputy of Research and Technology, Ministry of Health and Medical education), the High-tech Industry Centre, 2001 (Ministry of Industry), the Iranian Molecular Medicine Network, 2001 (34 research institutes and centers joined as members), and the Regional Health Genomics and Biotechnology Network, 2004 (Eastern Mediterranean Region, including centers from Jordan, Kuwait, Morocco, Oman, Pakistan, Saudi Arabia, Sudan, Syrian Arab Republic, and Tunisia).[10]

A long-term plan for the national biotechnology policy was prepared in 2004 in which different aspects of biotechnology in terms of education, research, production, and international relations have been defined.[11] Recently, the Ministry of Health and Medical Education (MOHME) has allocated a substantial grant specifically for biotechnology in all universities. This special grant reveals the overwhelming importance of biotechnology in the current 5-year plan of national development.[12]

The research activity and importance of biotechnology had a strong impact on the progress of this field in the country. More than four recombinant proteins in the area of bio-pharmaceutics are either produced or are in the process of obtaining permission to market. A wide variety of recombinant proteins for molecular biology and molecular diagnostic kits have been produced by private companies. A recent trend toward the export of biotechnology products manufactured by private companies has started.[13] It is noteworthy that some Iranian biotech products have been exported to Europe, South America, India, Egypt and Pakistan.[14]

Bioethics in Iran

Great Iranian physicians had paid special attention to ethics in their practices, teachings and manuscripts during different centuries.[15] Investigations into the medical ethical values of ancient Persian culture have proved more fruitful.[16] Zoroastrian priests had special emphasis and supervision on physicians' practice.[17] After Islam, inspired by Islamic teachings, Muslim physicians have placed emphasis on ethics in their practice. Given the religious emphasis on moral virtues, most of the famous medieval Muslim physicians would devote part of their books to medical ethics.[18] For instance, *Abu al-Hasan Ali ibn-e Raban Tabari* (AD 807-861), described in the book *The Paradise of Wisdom* (*Ferdous al Hekmat*) the Islamic codes of ethics.[19] *Mohammad ibn-e Zakariyya Razi* (AD 865–925) has also wrote some manuscripts on principles of medical ethics, and his book *Spiritual Medicine* (*Teb e Rohani*) is about ethics.[20] *Abu Ali al-Husayn ibn Abdahhah ibn Sina* (Avicenna, AD 973-1037), the well-known physician of the Islamic era, in his medical books has comprehensive moral advices about clinical medicine and physicians' practice.[21] Likewise, the ethical recommendations of *Ali ibn Abbas* Ahwazi (*Haly Abbas*, 930-994) to physicians, known as *Ahwazi Advises*, highlighted the ethics of medicine.[22] For thousands of years, ethics have been recognised as an essential requirement in the making of a physician in Islamic and Persian medicine.[23]

An emphasis on ethics has been voiced by medical and religious authorities in recent decades in this country.[24] A review of activities has been published in the *Eastern Mediterranean Health Journal*.[25] The compilation of a strategic plan for medical ethics activities was carried out in 2002 by the Research and Technology Deputy of the Ministry of Health and Medical Education.[26] The establishment of Medical Ethics Research Centre (1993, MOHME), organising the first International Congress of Medical Ethics (1993), development of Medical Research Ethics Committees at national level (1997), establishment of Medical Research Ethics Committees at universities and medical research centres, compiling and implementing the National Code of Ethics in Biomedical Researches all over the country have been its main activities in recent years.[27]

In recent years, professional education of medical ethics through MPH courses and periodical seminars and workshops in different regions of the country has been enhanced. Institution of PhD courses in bioethics is one of the future plans of MOHME. The Islamic Republic of Iran put forward the proposal of a special award in the name of 'Avicenna' in the field of ethics in science and technology to UNESCO, which was later adopted by this international institute (UNESCO). The Award consists of a gold medal of Avicenna (see Fig. 1) along with a certificate (the sum of $10,000) and a one-week academic visit to Iran. The winners of this award were chosen and introduced in 2004 and 2006.[28]

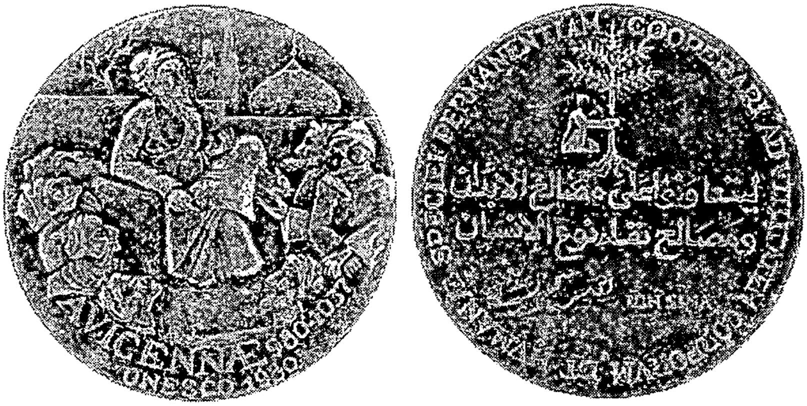

Fig1. The Avicenna gold medal.

As a result of the collaboration of scholars, scientists, experts, and those interested in the progress of bioethics in science and technology and making use of the immense national heritage and religious teachings, the Iranian Association of Ethics in Science and Technology was established in 2005.[29] It was an important step towards the closer collaboration of science and ethics in Iran.[30]

National Ethical Guidelines in Biomedical Research

Compiling the Specific National Ethical Guidelines for Biomedical Research was an important effort, undertaken as a joint project by the Medical Ethics and Medical History Research Centre (MEHRC), the Deputy Minister of Research and Technology of MOHME, and the Endocrinology and Metabolism Research Centre (EMRC) of the Tehran University of Medical Sciences (TUMS) in 2005. These Specific National Ethical Guidelines for Biomedical Research consist of: *Ethical Guidelines for Clinical Trials, Ethical Guidelines for Research on Minors, Ethical Guidelines* *for Genetic Research, Ethical Guidelines for Gamete and Embryo Research, Ethical Guidelines for Transplantation Research,* and *Ethical Guidelines for Research on Animals.* Similar guidelines and references from other countries are used in the initial compilation of these guidelines. The guidelines were reviewed and adopted by some law, ethics, medical and religious experts and the authorities of the Policy-making Council of MOHME.

The *Ethical Guidelines for Genetic Research* (see Annexure 1) and the *Ethical Guidelines for Gamete and Embryo Research* (see Annexure 2) are two important guidelines that should be taken into account in the field of biotechnology.

Considering the relatively high prevalence of genetic disorders in the country, there is a clear need for an organized development of services for these disorders with appropriate ethical supervision. Medical genetic ethics has been considered by Iranian specialists in recent years.[31] Currently, there is no absolute restriction on genetic research in Iran; however moral principles and ethical codes must be completely followed. Based on the *Ethical Guidelines for Genetic Research,* permissibility of genetic researches depends on the purposes (see Annexure 1). Moreover, prenatal diagnosis is permissible only if it is concerned with mother or foetus health, eugenic researches are prohibited. When a genetic testing is considered, a culturally adapted genetic counselling should be provided in an appropriate manner. In any kind of genetic researches, the best interests of the person concerned must be taken into consideration.

According to religious decree, human reproductive cloning is not permitted. Iran's Muslim Shi'a religious leaders have issued decrees authorising animal cloning. However, stem cell research and cloning for therapeutic purposes is permissible with full consideration and all possible precautions only in pre-ensoulment stages of foetus development.[32] Consequently, Iranian researchers of the Royan Institute reported the derivation of a new embryonic stem cell line (Royan H1) from a human blastocyst about two years ago.[33]

Abortion is a main issue of debate on the subject of prenatal genetic testing. The Parliament of the Islamic Republic of Iran approved a new Act on Abortion on 21 June 2005.[34] Previously, religious scholars had been allowed abortion in untreatable and genetic disorders with 3 criteria: definite diagnosis, before 4 months of gestation, and unusual problems for family. Under the new law, a pregnancy can be terminated within the first four months of pregnancy if the foetus is mentally or physically handicapped, or where the mother's life is likely to be in danger.[35]

Conclusion

As bioscience grows, a parallel structure grows with the same strength to provide assurance for people who are worried about negative applications or abuses of such growth.[36] In Iran, since capacity building in medical biotechnology has been the goal of different policy makers in last decade, we have been facing a good movement in biotechnology.[37] Now, appreciating all our scientists' efforts in the field of bioethics, appropriate ethical and scientific supervision of biotechnological programs should be enhanced to make sure that these advances are used responsibly, fairly, and humanely.

In the first step, ethics education for scientists and improvement of public awareness are essential for better mutual understanding of ethical challenges in the society. Addressing some ethical issues requires a continuing dialogue and cooperation between physicians, researchers, and religious scholars. Certainly, the biomedical and religious professions must be better prepared to deal with the increasingly complex issues in these fields. Certainly, socio-cultural backgrounds should be considered and reflected in the structuring and adaptation of the ethical guidelines and legal rules.

Endnotes

[1] Larijani (2006a).
[2] MBR (2005a).
[3] UNESCO (2005a).
[4] UNESCO (2005b).
[5] Tavangar (2005).
[6] Mahboudi (2005).
[7] Mahboudi (2005).
[8] Mahboudi (2005).
[9] Mahboudi (2005).
[10] Mahboudi (2006).
[11] Mahboudi (2006).
[12] Tavangar (2005).
[13] Mahboudi (2005).
[14] Mahboudi (2005).
[15] Larijani (2006a).
[16] Carrick (2001).
[17] Larijani (2006a).
[18] Larijani (2006a).

[19] Al-Ghazal (2004), Hamarnesh (1971), Levy (1957).

[20] Larijani (2006a).

[21] Larijani (2006a).

[22] Tajbaksh (2003).

[23] Amine (1981), Larijani (2006a).

[24] Larijani (2006b), Larijani (2005), Akrami (2004), Larijani (2004a), Larijani (2004b), Larijani (2004c), Zali (2003), Zali (2002).

[25] Larijani (2005).

[26] Larijani (2006b).

[27] Larijani (2005).

[28] MBR (2005b), UNESCO(2003).

[29] MBR (2005b).

[30] MBR (2005b).

[31] Larijani (2006d), Farhud (2000), Farhud (1999)

[32] Larijani (2004d).

[33] Baharvand (2004).

[34] IR Iran Parliament (2005).

[35] IR Iran Parliament (2005), Larijani (2006c).

[36] MBR (2005b).

[37] Mahboudi (2005).

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Annexure 1

Ethical Guidelines for Genetic Researches

Considering the ever-increasing advances in genetics, the emergence of new therapeutic technologies, and the special sensitive nature of human genetic data, and also recognising that human genetics is associated with some potential concerns regarding ethical issues, and reaffirming the importance of genetic researches for improving the public health and medicine, and recognising the importance of the ethical principles and norms, based on humanistic and Islamic foundations, and national laws in the researches of medical genetics, the ethical guidelines that follow are proclaimed for the researches in medical genetics.

The provisions in this guideline apply to the collection, processing, use and storage of human genetic data, human proteomic data and biological samples that are designed for researches. The cases of investigation, detection, and prosecution of criminal offences and parentage testing will be conducted according to the domestic law.

1. Medical Genetics Researches may be ethically permissible, only for the purposes of:
    a. Diagnosis, classification or screening of a hereditary disease or disability.
    b. Determining of vulnerability to a medical condition before emergence of its signs or symptoms, if effective interventions for reducing or preventing of its unwanted consequences are available, or the test's results are effectively and immediately related to the individual's decision-making for her/his future life or family planning.
    c. Genetic counseling for determination of the risk of hereditary diseases and disabilities in the offspring.
    d. Prevention, treatment, or palliation of diseases; and not eugenics.
    e. Forensic medicine and civil, criminal and other judicial proceedings, taking into account the domestic laws.
    f. Population-based genetic studies, taking into account the scientific and ethical principles.
2. When the collection, processing, use and storage of human genetic or proteomic data, or biological samples are carried out in two or more countries, the proposed research must be assessed and approved by the national medical research ethics committee of Iran and then by the appropriate ethics committee in the other countries concerned. It should be mentioned that the approval of all ethics committees are necessary for initiation of the research.
3. When the collection, processing, use and storage of human genetic or proteomic data or biological samples are carried out in two or more universities or research centres, the proposed research should be assessed and approved by all of their research ethics committees.

4. Every effort should be made to ensure that human genetic or proteomic data are not used for purposes that lead to discrimination or any type of infringing of fundamental freedoms or human dignity or for purposes that lead to the stigmatization of an individual, a family, a group, or communities.
5. For collecting human genetic or proteomic data or biologic samples or taking photos or videos, the consent of research participants should be free, informed, and express and without inducement by financial or other gains. The informed consent is necessary for any processing, use or storage of these data, carried out by public or private institutions.
6. In cases of incompetent people who are incapable of giving informed consent, authorization should be obtained from the legal representative, in accordance with domestic law. The legal representative needs to take into consideration the best interest of the person concerned.
7. An incompetent adult should as far as possible take part in the authorization procedure. The opinion of a minor, in proportion to his or her age and degree of maturity, is a determining factor and should as far as possible be taken into consideration.
8. Diagnostic and treatment services, screening, or genetic tests in minors or incompetent adults, will be ethically acceptable, only when there are definite profits for the person's health and his/her best interests are taken into consideration.
9. When human genetic or proteomic data or biological samples are being collected for medical and scientific researches, the participant can withdraw his or her consent, unless they are irretrievably unlinked to the person concerned. According to the regulations, withdrawal from the research should entail neither a disadvantage nor a penalty for the person concerned.
10. When a person withdraws consent, his/her genetic or proteomic data or biological samples should no longer be used, unless they are irretrievably unlinked to the person concerned.
11. It is ethically imperative that when a genetic testing that may have significant effects on a person's health is being considered, genetic counseling should be provided in an appropriate manner. Genetic counseling should be culturally adapted and consider the best interests of the person concerned.
12. When the research may reveal the information which has potential effects on the future of the participant or his/her family, the research protocol should include issues such as consent, counseling, support, quality of testing, and confidentiality. Otherwise, such researches should be approved only if the source of the genetic materials is irretrievably unlinked to the person concerned. Counseling and prediction of the results of research should be accomplished by appropriately trained health care workers who have sufficient experience.
13. Participants with hereditary disability or disease, asymptotic carriers of disease and also at-risk persons (proven or suspected) should receive

necessary information regarding the available diagnostic or therapeutic options for their conditions, at the appropriate time and in an appropriate manner. Furthermore, if the treatment of a participant's relatives is necessary, the researcher should inform him/her, after obtaining the consent from the participant or his/her legal representative.

14. Genetic counseling should be non-directive, free of pre-judgment and non-judgment.
15. No one should be denied access to his/her own genetic data, unless such data are anonymous or the domestic law limits such access.
16. Human genetic and proteomic data and the biological samples should not be used for a purpose different from the one mentioned in the obtained consent, except after obtaining the informed, free and express consent, or if the purposes are in conformity with domestic law and the interests of the community.
17. Researches in which obtaining of an informed, free and express consent is impossible, or data retrievably unlinked to identifiable persons, should be done only with approval of the research ethics committee.
18. Benefits resulting from the researches on human genetic data should be shared with the society.
19. Prenatal diagnostic tests should be done only if they are related with the health of the mother or her foetus.

Annexure 2

Ethical Guideline for Researches on Gamete and Embryo

Human scientific knowledge in the fields of reproductive biology and biotechnology has been greatly expanded in the two recent decades. These developments began with using the extra uterine fertilization techniques and thereafter, the Assisted Reproductive Technologies (ARTs) have been developed in a fast manner. Consequently, different ethical issues have arisen in this regard answering which requires serious and exact deliberation. Although there are different opinions regarding the status of human gametes and embryos, it is accepted that they should not be considered as mere tissues and any researches on them require obtaining the appropriate consent of the persons who are responsible for the embryo, including the donor, her partner, the recipient, and her partner (this differs from the donor).

1. Researches on the human gamete and embryo and the therapeutic plans of ARTs should be conducted with a profound respect to the human dignity of all the participants.
2. Researches on the surplus embryos of ARTs require authorization from who are responsible(s) for the embryos or their legal and juridical guardian and the research ethics committee.
3. If the research includes clinical treatment, the risk of harm should be proportionately outweighed by the benefits resulting for the participant. In researches for obtaining new information, no additive risk is justifiable.
4. Participation in the research should be completely voluntary, informed, and free of any kind of pressure. The purpose(s) of the research should not be hidden from the subjects.
5. In all research proposals, it should be mentioned that the process of informing and obtaining the consent is completely separated from the process of treatment of the patient.
6. Researchers should carefully record the information on the biological origin of the gametes and embryos. Keeping the accuracy and privacy of the information is necessary.
7. Disclosure of private information of the participants should be done only with the legal authorities' approval.
8. The participants should not bear the costs of the research.
9. Researchers should ensure that the probability of unwanted complications for the embryo or the future child is minimal.
10. The ovum or sperm used in the research should not be obtained by commercial means.
11. Production or attempts to produce hybrids using human and animal gametes, transferring of the nucleus of somatic cells or sex cells between human and animals, or any similar activities are forbidden.

12. In the cases that appropriate alternatives exist, the research should not be done on human embryos. Producing the human embryo for research purposes is forbidden.
13. Embryos that are used for producing pregnancy are not considered as surplus embryos. Research on them is acceptable only if the results could not be obtained by any other kinds of researches.
14. Researches which include destruction of the embryo should not use the embryos over 14 days of age (after conception). (The period in which the embryo was frozen, is not taken into account.)
15. In the transformation process of a human gamete or embryo to a foetus, changing the genetic content is prohibited.
16. The number of embryos that are used in research should be the minimum required for the purpose of the research.
17. Researcher should ensure the recipients that if they refuse to participate in the research, their treatment won't be influenced.
18. The embryos which are not surpluses of the ART process should not be used outside of the woman's body for purposes unrelated to the ARTs.
19. The responsible persons for the embryo are the donor, her partner, the recipient and her partner (this differs from the donor).
20. Researchers should ensure that all the information related to the research and clinical cares of the embryo are available for the responsible persons of the embryo. The explanations should be in accordance with the sensitivities and capacity of the responsible persons.
21. The responsible persons can withdraw their consent whenever they want.
22. The informed and written consent should be obtained from the couples whose embryo is to be used in the research.
23. Although the autonomy of the couples regarding donation of their embryo's tissues is respected, the mother does not have the right to make the use of these tissues exclusive for special persons, such as her family members.

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Redesigning the Production of the Bacillus thuringiensis Bio-Pesticide within the Context of Subsistence Agriculture in Andhra Pradesh, India

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Abstract: Biotechnologies are social constructions. The way in which biotechnology is designed, developed and deployed depends on the actors involved in these processes and the strategies and choices employed by these actors. This article assesses the re-designing process of the production of a biopesticide based on the extracts of the soil bacterium Bacillus thuringiensis (Bt) by local networks. The new Bt product attempts to address the Castor-Semilooper management problems of resource poor farmers in the rain-fed agriculture systems of Mahaboobnagar and Nalgonda in the state of Andhra Pradesh, India. It is argued that the development of biotechnologies in a local self-organized environment and the incorporation of certain social issues in the new products could lead to technologies attuned to the local potentialities and constrains. During the redesigning process the new Bt product has acquired a new material form and political social content.

Keywords : *Bt Bio-Pesticide, sociology, Subsistance Agriculture, Andhra Pradesh*

Introduction

Next to the efforts of private and public institutions to relate the development of biotechnologies[1] to the narrow framework of an increased industrialization of agriculture, there are also initiatives of

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multi-stakeholder networks to tailor biotechnologies to local sustainable developments.[2] Both types of initiatives are characterised by making different technological choices to manage biotic stresses, resulting in different techniques of pest management.

This article assesses the ongoing experience of the Andhra Pradesh Netherlands Biotechnology Programme (APNLBP)[3] to redesign the production of biopesticides[4] based on extracts of the soil bacterium *Bacillus thuringiensis* (Bt) in order to strengthen the development perspectives of small scale agrarian systems in the dry-land districts of Mahaboobnagar and Nalgonda of Andhra Pradesh, India. The new Bt product is applied to control the Semilooper (*Achea janata*) pest on the Castor crop. Therefore, by relating the technology's development to the context of the village economy it is claimed that a significantly different Bt bio-pesticide is emerging which is unlike the Bt-resistant plants and sprays delivered by multinationals. The Bt product is characterised by the following two core elements.

First, the techniques are designed to facilitate an organization of the Bt production process based on primarily (though not exclusively) *locally available resources*, such as local (informal and formal) knowledge, local strains of Bt effective against the local pests, and local labour-force.

Second, the *political control* over the development of the Bt technology has been reorganised towards an increased involvement of multi-stakeholders platforms in the design, production and deployment of the new Bt product. Consequently, it will be shown that the bottom-up technological development together with the conquered space for negotiations by farmers and civil society organisations on the design of the Bt product are reinforcing each other in such a way that the biopolitical dimensions of the Bt product are reshaping the social agrarian landscape of Andhra Pradesh.

By reflecting on the design, development and deployment of the Bt bio-pesticide, this article attempts to illustrate how the development of biotechnologies in a concrete self-organising social environment and by incorporation of certain social issues in the technological developments, could lead to new products which could address the needs of resource poor farmers. Furthermore, it is the intention of the paper to add empirical data to the debate in the social sciences about the possibilities to reorient the developments of biotechnologies from an exogenous development dominated by large agro-industrial corporations to a process in which specific social issues can be introduced in the design of new biotechnologies and products.

The article is structured in four sections; following this introductory paragraph, the second section addresses the social relevance of Bt-products both for large-scale and small-scale farming systems in Andhra Pradesh, India. The third section tackles the reorganization of the local available resources for the production of the Bt product. The fourth section deals with the political issues raised by the redesigning process. Therefore, the article argues how the design, development, and deployment of the Bt bio-pesticide related to the developmental perspectives of village economies have also changed the Bt product itself giving it a new material form and social content. Finally, the philosophical and political implications of this new approach for biotechnological developments within the field of science and technology studies are discussed in the last section.

Social Relevance of the Production and Use of *Bacillus thuringiensis* for Indian Agriculture

The big majority (70 per cent) among the thousand million inhabitants of India live in the countryside. Approximately 35.6 per cent (390 million) of the population must survive with less than a dollar a day.[5] This research was conducted in Andhra Pradesh (AP) which is India's fifth largest state by population and fourth largest state by area. AP can be broadly divided into three regions, namely Costa (Coastal Andhra), Telanga (west on the Deccan plateau) and Rayalaseema (southeast on the Deccan Plateau).

More specifically, the study was conducted in the Mahaboobnagar district, the largest district in the Telangana Region and the second largest in AP, as well as in the Nalgonda district. The rural population in these districts forms 90 per cent and 87 per cent respectively of the total population. The districts are located in the semiarid region of India with recurring meteorological drought and worsened by overexploitation of meagre groundwater resources.

Many problems affect the life and work of small scale farmers in those areas, like drought, low yields, or pests. Agriculture in the area is rain-fed and the districts are plagued by extreme poverty. The main crops cultivated in the districts are castor, red gram, sorghum and groundnut. Of these crops, Castor[6] is the most important one, occupying 27 per cent of the cultivated area in Mahaboobnagar and 20 per cent in Nalgonda. Furthermore, many insect pests constrain the cultivation of this crop in these dry regions. One of the most important is the Semilooper (*Achea janata*) that causes heavy losses of up to 20 per cent of the total yield.[7]

In fact, pest management is a complicated activity in this context because most commercial products are not affordable by small-scale farmers and moreover these are not trustworthy dealers.[8] In addition, the toxicity of the available chemical pesticides causes health problems to farmers. Farmers are often unable to read the pesticide's instruction labels (either because they cannot read or do not understand the language on the labels) and they don't have the necessary means for protection, like masks. Moreover, the massive use of pesticides has degraded the fertility of the soils and caused problems for non target organisms.[9]

AP is one of the major consumers of agro chemicals in the country.[10] However, there has been a significant decline in pesticide consumption during the past decade. The level of pesticides consumption in the State during 2003-2004 was expected to be around the 3.600 tonnes in contrast to the 13,650 tones used in 1992-93. The officials of the State Agricultural Department attribute this decrease to the adoption of integrated pest management practices and growing awareness among farmers of the risks attached to agro chemicals.[11]

In addition to chemicals[12], many other methodologies are used to manage the castor semilooper. For instance, hand picking and killing of older larvae of semilooper is an effective method practiced by some castor growers. Moreover, some efforts were made to control the pest by releasing parasitoids eggs (*Trichogramma chilonis, Telenomus proditor*). However, this practice has not gained popularity among farmers because of the complex set of requirements for an appropriate use.[13] Other biological controls effective against semilooper are the neem seed extracts and many other neem formulations. Finally, the bacterium *Bacilus thuringiensis* has been found effective against semilooper.[14] This article focuses on the development of one biopesticide spray formulated on the basis of Bt, to control the castor semilooper.

The *Bacillus thuringiensis* as a Bio-Pesticide Alternative

Bacillus thuringiensis (Bt) is a soil bacterium. The insect pathogenic activity of Bt is a natural process occurring in the daily organic life of farmers' fields. Bt has toxic effects against certain insects (of Lepidoptera, Coleopteran and Dipteral families). However, Bt is considered to be safe to humans and other mammals.[15] Also, it is highly specific and therefore safe for non targeted insects.[16] Furthermore, Bt could be the beginning of a long series of new and expected safer technologies to augment productivity and to bring about a more sustainable agriculture. Within Bt alone, there are already over 50 genes with known insecticidal properties.[17] It is the only microbe which has been successfully commercially exploited for the management of insect pests. Therefore, Bt products form 95 per cent of the world market of microbial pest control agents.[18] Since the discovery of the mechanisms of its toxicity (in the fifties), Bt based formulas have been used as an effective bio-pesticide in agriculture.[19]

Three main technological trajectories have been followed for the production of Bt based products:

- Recombinant DNA techniques
- Biopesticide Bt-spray (liquid state fermentation)
- Biopesticide Bt-spray (solid state fermentation)

Recently, researchers have transferred certain genes from Bt to some plants, in order to create crops that produce their own insect toxins.[20] However, the development of this technology has provoked a fierce pro-contra debate. In spite of the great expectations of some researchers, the sceptics expect that insects could develop resistance to the massive use of Bt, especially when it is genetically transferred.[21] In addition, a cross-pollination between biotech and non-biotech crops may occur.

Many critics are based on the fact that the life-science corporations (joint business of agro-chemical and biotech companies) heavily control the commercialization of Bt.[22] Fifty-seven percent of all Bt patents have been issued to only eight companies (Monsanto, Novartis, AgrEvo[23] and Mycogen with their own technologies, and DeKalb Genetics Corporation and Pioneer Hi-Bred International through strategic alliances).

In India, some Bt transgenic crops are grown, but because of their high prices, most of the time, resource poor farmers are excluded from their use.[24] For instance, the use of Bt-cotton seeds implies increasing investment in terms of purchasing seeds, fertilisers and pesticides. Farmers frequently need to take loans to be able to afford such costly inputs, but in the case of disappointing harvests or crop failures, these farmers are left with high debts, as the high interest rates are very difficult to repay.[25] Moreover, so far most efforts have been oriented to develop crops of major agrarian and commercial importance, bypassing minor crops like Castor.[26]

In addition to the DNA recombinant trajectory, there are two major methodologies to manufacture the Bt bacteria in a bio-pesticide: solid state fermentation and submerged (liquid state) formulations.[27] Formulation is a crucial link between production and application and dictates the efficiency[28] and economic viability of the final product. Moreover, the maximal production of Bt's toxin[29] can be achieved only by paying careful attention to the interaction between fermentation conditions, media and the Bt isolates involved.[30] Furthermore, the sustainability of the production process is related to:

- cost of raw materials
- strain efficiency
- degree of automation required
- continuous power supply
- required degree of technical skills.[31]

The cost of raw materials is one of the principal expenses involved in overall Bt production. In the conventional (industrial-liquid state) production process, the cost of raw materials varied between 30 and 40 per cent of the total cost depending on the plant production capacity.[32] Therefore, local production of this insecticide in resource poor rural areas should depend on the use of production media made of cheap, locally available resources.

Although the efficiency of the commercial formulations has been proved (for the agrarian contexts with the required economic capacities), the submerged fermentation may not be economically feasible for resource poor rural areas due to the related high costs of technicians and automation (deep-tank fermentor, high speed cooling centrifuge as well as drying facilities e.g. spray dryer.[33]

In India, Bt bio-pesticides have been produced by the liquid state fermentation. The companies involved in this method to manufacture biopesticides were importing the technical materials and producing the Bt in India.[34]

This commercial strategy has not succeeded in developing suitable technologies for small scale agriculture because it requires:

- high capital investment
- high level of automation
- high technical skills
- continuous power supply[35]

That is why solid state fermentation emerges as a feasible methodology for those regions of the world that lack human and economic capacities to reproduce the liquid state fermentation. Advances of the solid state fermentation are:

- low cost of the methodology
- low capital investment
- low level of automation
- low technical skills
- low amount of wastewater.[36]

Solid state fermentation is a critical methodology for the production of efficient locally oriented bio-pesticides in developing countries; nevertheless, little has been published on the subject.[37]

In summarising this, within the narrow context of an industrialising agriculture, no suitable pest-management technique has been developed attuned to the potentialities and constrains of resource poor farmers in the dry agriculture of these regions. This article focuses on the dynamics engaged in by local networks to redesign the production of a Bt biopesticide from a liquid state fermentation to a solid state fermentation for the management of the Castor-Semilooper. This article attempts to gain in understanding the social construction of technology and of the technological construction of society.

Bt-Spray's Redesigning Process

The Reorganization and Mobilization of Natural and Human Resources available within the Locality

In this section we will follow the Bt chain, from the isolation of the bacteria in farmer's fields, to the lab, and from there to the production units and back to the fields where the product is used. Therefore, we witness how the formal and informal knowledge of the local labour forces (from researchers to farmers) jointly reorganise the use of the available natural resources (like Bt strains) to develop appropriate biotechnologies for the local circumstances. Finally, the section addresses the main bottlenecks for those purposes.

The APNLBP network coordinates the Bt biopesticide redesigning experience. Commonly, APNLBP organises its different projects[38] as follows; first, they define the problems that have priority for resource poor farmers and could be addressed through biotechnologies. Second, the programme looks for different social agents with the skills required to develop the biotechnological choice.

Naturally, the Castor-semilooper emerged as one of the major problems for farmers in Mahaboobnagar and Nalgonda. Therefore, researchers, NGO's and farmers met and exchanged their agrarian knowledge about the management of Castor-semilooper. The available pest-management techniques were discussed. Farmers formulated the problems caused by the semilooper and the inappropriateness of, and problems caused by the commercial formulas. During those discussions the search for a cost-effective redesign of Bt-spray was decided.[39]

Moreover, isolation of the local Bt strains was decided upon, rather than the use of commercially available formulas, for two main reasons. First, in India, in order to promote Bt for pest management, the final product requires to be registered by the Central Insecticides Board (CIB). Their guidelines permit only the registration of formulations which employ local isolates. Second, local isolates seem to have a better capacity to withstand the environmental stresses in the field and can persist longer. In order to isolate these local strains, researchers of the Directorate of Oilseeds Research (DOR) and farmers collected samples of soil and dead larvae of Castor-semilooper in farmers' fields.

Afterwards, the local isolates of Bt were analysed by the microbiologist of the DOR in Hyderabad. In India, a molecular analysis is required when a large use of the pest-management product is expected. Moreover, genomic DNA from the samples was analysed (using the Polymerase Chain Reaction with three sets of primers *viz.* ERIC, BOX and REP) to identify which species and subspecies of Bt were present in the isolates and what cry genes were there (cry gene profiling). Furthermore, a total of 120 local isolates where used for further analysis. They were compared with the commercial isolates (Delfin from Margo Biocontrol Pvt. Ltd., Dipel from M/s Cheminova, and Halt form Wockhardt Ltd.) and with five strains purchased from the Ohio State University (USA) to evaluate their efficiency against the semilooper.[40]

After that, several bioassays in the lab were performed, followed by various tests in farmers' fields (in collaboration with farmers). Two local strains were found to be very effective in controlling semilooper under field conditions. DOR-1[41] was chosen for further mass multiplication.

Mobilization of the Local Labour Force

Throughout the field trials, scientists shared their knowledge with farmers. Both groups gained further understanding about the management of the pest by Bt under field conditions. At the moment, farmers are able to decide the best moment to spray. Moreover, in the fields where farmers managed the semilooper with chemical pesticides like quinalphos, four or five sprays of the insecticide had to be applied while the pest could be managed in Bt sprayed fields with only two sprays. This is because the natural enemies like *M. maculipennis, Euplectrus maternae,* and several others leading to natural pest suppression of the pest in the later stages survived the Bt-spray.[42] Furthermore, farmers are able to detect if the deceased semilooper larva died because of the Bt spray.[43] As far as they are concerned, scientists recognise the crucial element of involving farmers at all the stages of biotechnology development, allowing them to understand the nuts and bolts of the technology. Also, as some of them declare, to "easily get the acceptance of the technology by farmers and therefore, avoid the possible rejection of the technology in some of its latest stages". However, in this article the collaboration between the different kinds of knowledge is perceived not as a means to get acceptance of the technology but as an end in itself. Therefore, at this stage we are confronted with an issue of a moral nature. Allow me to restructure as a question what was originally a statement of Richard Sclove (1995): "is it a kind of moral right or a matter of justice, that people should be able to influence the basic social circumstances of their lives?" If our answer is affirmative, this view may imply for instance, that farmers should get access to decision making in biotechnology along relatively egalitarian and participatory lines.[44] It is not only morally appropriate but it could also be more efficient. Therefore, because of the rural dispersion of villages, a decentralised system of small scale biotechnology units seems a good option for farmers to exercise local control over and get access to the negotiations around the development of pest management techniques. Consequently, it is possible to gain efficiency, for instance, in the supply of the final product.

The mass production of Bt spores was redesigned by developing an alternative to the conventional liquid state fermentation. This alternative implied the multiplication of Bt by its fermentation in a solid medium in which *local agricultural wastes/by products were used,* such as wheat bran and molasses. Since magnesium, manganese, iron, zinc and calcium ions are present abundantly in wheat bran, the need to supplement these ingredients in the medium has been overcome, reducing (a small share of) the costs. Moreover, it has been decided not to invest in costly fermentors, but to use *plastic basins* in which the multiplication of the Bt-isolates takes place and in which the wheat husks are used as a medium for Bt-multiplication. Multiplication in plastic tubs brings the cost of production further down because of the low costs of plastic tubs as well as their re-usable nature when compared to the use of glassware. The latter is costly as well as easily subjected to fracture.[45] Because the inoculations are carried out separately in different plastic basins, mistakes would only lead to the loss of a small amount of the inoculated medium in some of these plastic basins. In this production process risks are spread out over more units, whilst within the submerged fermentation process a falling out of electricity power may completely destroy the inoculated medium.[46]

In addition to the use of local agricultural wastes and plastic basins a third innovation of the Bt networks is that the inoculated medium within the plastic basins can be kept in a room for around 65 hours and be carried out at the villages level. Aeration is provided every eight hours after the second day in a laminar air-flow cabinet or in a chamber where the desired conditions of a laminar air-flow are simulated. This aeration system also implies that the production can be *decentralized* and carried out in biotech units at the village level. The downstream processing for obtaining the final product is carried out through *centrifugation* in which the medium is filtered with distilled water. The supernatant containing the beta exotoxin is discarded. The pellet containing the spores and crystals of Bt is mixed with the carrier, *shade dried and powdered* with a kitchen coffee mill. The final Bt product *is mixed with water* by the farmers in the fields and *sprayed* on the Castor.

Due to the low skills required for the Bt-spray production and to cover the growing demand of the non toxic and effective product by local farmers, the NGO's (SDDPA and GMM) involved in the project have assumed the responsibility to produce the spray, at an affordable price, in mass multiplication centres in different villages spread over the region. These centres are assisted by scientists of the APNLBP's partner research institutes. The units seem to be able to guaranty the product supply at farm level. Young local biotech technicians are working on these centres; most of them are sons and daughters of local farmers.

To develop biotechnologies in tune with the natural and social environment, the APNLBP tries to mobilise the available resources and therefore the existing biotechnologies. Both the high and low-technologies are separately used in some projects (like vermiculture or recombinant DNA) and mixed in others. For instance, for the redesign of the Bt-spray, the latest genomics techniques (e.g. sequencing of the genome of BT DOR-1) have been assembled with a traditional solid state fermentation. By doing so the programme has won the confidence of farmer communities because of the tangible and quick results provided by the low-tech biotechnologies.[47]

Finally, the large-scale field trials of DOR Bt-1 formulation in Mahaboobnagar and Nalgonda districts have shown that the pest can be managed with two sprays at 15 day intervals. The pest-management's costs have been reduced threefold when compared to the chemical insecticide. The final Bt product *is mixed with water* by the farmers in the fields and *sprayed* on Castor. Around 100-150 l of spray suspension is required per acre for the management of Castor semilooper depending on the stage of the crop. The material cost for production of one kg Bt would be Rs. 32[48] (about 1 Euro).[49]

Bottlenecks for Sustainability

Although the intention of this article is to understand the social and technical changes that occurred during the efforts made by the local Bt networks to develop a new biopesticide appropriate to the local conditions, it is also recognised that redesigning is still an ongoing process in the tryout phase. Therefore, some bottlenecks may that threaten the sustainability of the biopesticide's redesigning process have been identified.

In my view, the collaboration efforts and new partnerships between the pluriform set of actors involved in the redesign process should be a long-term route; first because of the obvious benefits of inclusive dynamics for poverty alleviation. Second, it seems important to make an assessment of the performance of the Bt-spray over a period of time; for instance to avoid the emergence of possible resistances of the Castor-semilooper to the DOR Bt-1. Third, once the Bt production is fully assumed by the local NGOs, some technical problems may appear that will need the support of scientist from the DOR in Hyderabad. Finally, it is important to monitor possible future health problems which are unexpected though at this stage still might emerge from a massive use of bio-pesticide in those two districts.

In order to guaranttee the long-term stability of this decentralised production, collaboration between local producers and scientists is vital. However, this long-term collaboration of the network can be jeopardised by the lack of reflection (and motivation) of the individual human actors belonging to the Bt-spray network. For instance, some scientists do not feel as if they belong to a network beyond their research institute. For them the Bt spray is "one more of their projects" which requires a 'peculiar' methodology with more visits to the field than usual. Similarly, most of the NGO staff members working at the multiplication centres seem to develop a routine laboratory labour to earn their wages.[50]

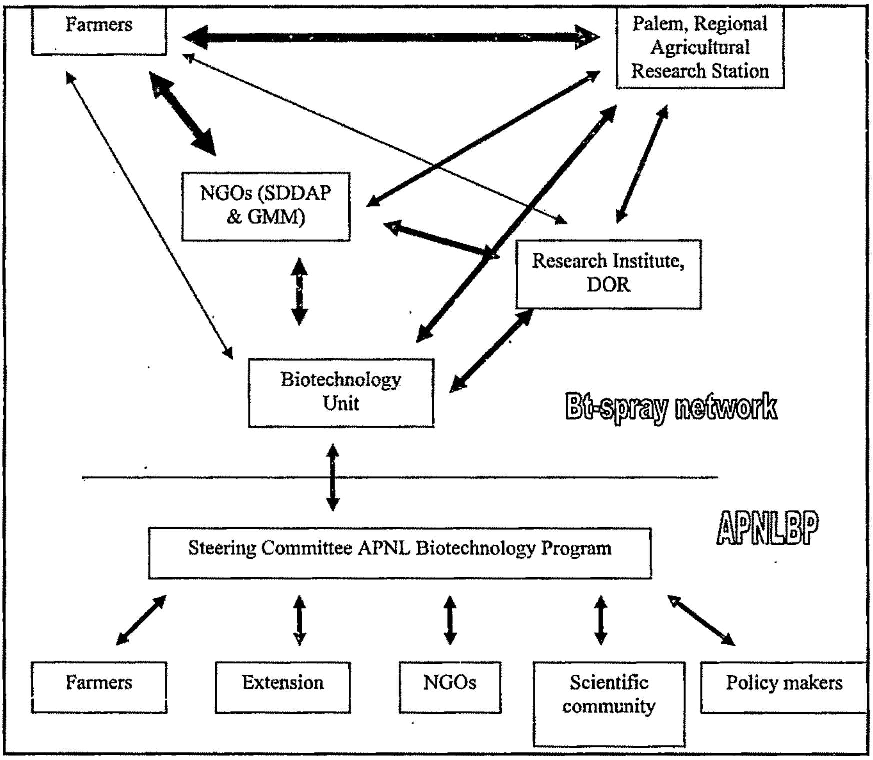
Another bottleneck in relation to the available human resources is the difficulty in finding (young) researchers to occupy positions in the isolated rural areas. Unfortunately, this brain drain, from villages to cities and form India to other countries, is taking place at all levels of Indian society.[51]

In this section we have analysed how by a reorganization and mobilization of the local human and natural available resources, the new Bt bio-pesticide has been redesigned and has emerged as highly effective, non-toxic and affordable for farmers. Furthermore, the redesign process has been possible as a result of the control exercised by the multi-stakeholder network in the process. The next paragraph attempts to understand the politics of that process.

The Self-Management on the Bt-Spray Redesigning Process- A Try Out

To understand the APNLBP programme we should realize that the Dutch Ministry of Foreign Affaires (financial institution of the APNLBP), from the very beginning, decided to delegate the responsibility of the management of the projects to a local steering committee (Fig. 1). The Biotechnology Unit (BTU) is an autonomous body inside the institutional public scientific agrarian research system, and it s led by a multidisciplinary team. The task of this unit is to coordinate and monitor more than 60 projects which are developed in the APNLBP. The decisions of the BTU, based on scientific analysis, are in principle recommendations that have to be validated by the steering committee which has a more holistic view over the regional reality because of the plurality of its members.

One of the interesting features of the APNLBP is that it follows an Interactive Bottom Up (IBU) approach.[52] The aim is to formulate all the projects and programmes on the basis of local needs assessment and priority setting. Consequently, in the first stage of the programme's projects workshops are organised in which farmers, researchers, governmental and non-governmental organizations are involved. This should lead to a decision making about the most appropriate biotechnological path for the local context, to be followed. Moreover, one of the important elements of these workshops is the presence of NGOs. The NGOs involved in the project mobilize the local labour force (farmers or technicians) and integrate and stimulate the use of local resources. In the same way, research institutes involved get experience to work with local resources; like crops and their pests.



Note: The thickness of the arrows indicates the intensity of the relation. The arrowheads indicate the direction of the relation.[53] Acronyms: APNLBP- Andhra Pradesh, Netherlands Biotechnology Programme. DOR - Directorate of Oilseeds Research; SDDAP- Society for Development of Drought Prone Area; and GMM - Grameena Mahila Mandali.

These workshops were also the starting phase of the development of the new Bt product. Therefore, once the problem was identified (Castor-semilooper) and the biotechnological choice defined (Bt-spray), an apparent regular interaction has taken place between the farming community and the scientists while developing the technology. As a result, an opening is created for civil society organizations and farmers to get some control (larger or shorter) over the development process of biotechnology. The engagement of the network on participation dynamics unlocks the opportunity to integrate farmers' knowledge and experience in the development of new biotechnologies. Nevertheless, there are moments during the development of the Bt-spray when the presence of a certain kind of actor is crucial, and where the decision making capacity of other actors is rather small (as it is the case during the characterization process of isolates by molecular biologist).

Moreover, these dynamics open not only the possibility for larger sectors of the population to plan and organize the development of biotechnology, but it also offers some control for farmers and civil society organizations on the deployment strategies. The deployment of the Bt biopesticide takes place in the rural areas. In this way, the *benefits and responsibilities coming out of the Bt redesign process can be regionally redistributed.*

Consequently, micro-enterprises have been created in some villages for the production of the final Bt powder. Those units are run by the local NGOs and technically supported by the research institutes. It is also important to notice that those micro-enterprises are not only producing Bt. In their labs other bio-pesticides (like trichoderma or baculovirus) are also developed. In some cases these labs are integrated in what is called a bio-resource centre, with the facilities to manufacture other kind of bio-pesticides and fertilisers like vermiculture or Neem tree products. Furthermore, the programme has the intention to promote these decentralised bio-resource centres as (economical and organizational) autonomous units.

These bio-resource centres seem to have some potential to become a catalyst for local agrarian development. In these centres the heterogeneous set of social agents (researchers, farmers and NGOs) converges to coordinate the production of the new bio-pesticide. In fact, the bio-resource centres are situated at the village level; this facilitates the access of farmers to information about the product (use, risk or quality) and it offers them a certain control over the units.[54] However, future studies about these experiences will address to what extent the control exercised by the farmers can be defined as significant and how far the new emerging biotech elites, in the social form of NGOs, are more effective to address the problems of resource poor farmers than the research stations (situated at the farm level)until now.

Public and Private Sector Engagement in Local Biotech Programmes in India

This section addresses the local biotechnology redesigning processes viewed against the background of the broad Indian national biotechnology developments. The aim here is to develop a further understanding of the significance of the political reorganization around the production of the Bt-spray.

India has a very strong *public-sector* concerning agrarian science and research infrastructure; however, it seems that this system is organised around a centralised model of technology development and transfer that could jeopardise its usefulness for resource poor farmers. Some important elements of this situation are, for instance, the strong hierarchies and separation between research, extension and farmers. It has been described as a 'hard science' approach which gives less importance to sociological matters, and which tends to perpetuate the hierarchy of science and society and the patterns of control that this implies.[55] However, the work of the described Bt-network here is unthinkable without the structures and persons working in the Indian public sector (see Fig. 1). In fact, two good examples of this public presence in the project are the Biotechnology Unit in Hyderabad, which coordinates the project and the research institute called Directorate of Oilseeds Research (DOR) that has done the molecular analysis and developed the novel Bt multiplication methodology.

Next to the extensive public sector, the *biotech private sector* grows rapidly in the country.[56] Moreover, there are special biotech-plans for the different states which promise fiscal and infrastructure support measures to prospective entrepreneurs. In the concrete case of AP this has lead to creation of the Genomics Valley in Hyderabad (mainly pharmaco-genomics oriented) where private companies have the leading role. These companies are first and foremost focusing on markets to reimburse their expensive investments in R&D. Therefore, they have little incentives to develop products for resource-poor farmers since farmers lack the economic capacities to pay the product's high prices. The high prices are required to recover those investments.[57]

Other scientists who have analyzed the APNLBP network[58] have mentioned the absence of the private sector in the programme. This absence is understandable, in the initial phases of the programme, not only because of the absence of private companies in those rural regions, but also because (as mentioned before) resource poor farmers lack the economic attractiveness which is necessary to become a target group for the private sector. However, some traces of private sector participation do emerge in phases close to concrete moments in the development of some products. For instance, due to the lack of genome sequencing infrastructures in the public research institutes and universities involved in the Bt-spray project, and because the compulsory official registration of the product, the services of some private companies[59] are required to map the genome of the most powerful Bt isolate found against the castor-semilooper.

Going deeper into the Indian landscape; poverty is concentrated in the rural areas that, according to the World Bank,[60] are the home for three quarters of India's poor. This situation is also true for the state of Andhra Pradesh, where due to the bad public sector performance in those rural areas, a breeding ground is created for the growth of radical movements like Maoists guerrillas and the multiplication of NGOs that are filling the space that the government is not able to cover. Moreover, developmental NGOs and intermediary research provide a critical link between farmers and scientists in initiating decentralised participatory plant breeding or other biotechnological developments at "left behind" locations.[61] These *civil society organizations* are essential to open the *room for manoeuvre* for a wider sector of the population in the development of (bio) technologies. This is because of the high degree of collaboration between NGOs and farmers. During the development of the Bt-spray the high level of trust between farmers and the NGOs involved in the project has been decisive; this is because the design phase of the pest-management techniques is a long-term process, and the return from the labour investments is uncertain.

The Politics of the Bt-Spray

We have witnessed the efforts of the Bt-spray networks to manage the political reorganization of the natural and human resources to develop an appropriate pest-management technique in the rural context of

Andhra Pradesh. Herewith, the traditional top-down Indian model of biotechnology developments[62] has been reversed in a way into a kind of bottom up approach where the whole set of actors is, to some extend, involved in the different phases of the Bt-spray's development.[63]

The redesign and reorganization of the production of the Bt-spray takes place within the global context of industrialisation of agriculture. As we have seen before (Section 2), this historical context has not been able to develop suitable pest-management alternatives for resource poor farmers in these regions. Moreover, some philosophers have analysed how the political and politicising elements involved in the development of biotechnologies within this global industrialization process are creating new identities by shaping the social context in which the techniques are implemented.[64]

The industrialization process of agriculture has been possible by the deployment of the next three political characteristics and politicising consequences:

- The *industrial appropriation* of some key farming activities, like crop and pest management by external institutions through the supply of industrial inputs.[65]
- The *scientification* of agricultural research has taken place. Subsequently, it has produced an increasing prescription of farming practices from the scientific domain.[66]
- With the biotechnologization of agriculture a *remote control*[67] (control at a distance) on different farmers activities has emerged.[68]

These three developments are challenged by the strategies of local self-organization in the production of the new Bt-spray. For instance, the *industrial appropriation* of farming activities by external institutions is reversed by the self-organized practices of local networks to create their own pest-management technique; by isolate, select and multiply Bt within the locality.

The *scientification* of agricultural research is challenged by the creation of horizontal structures of multi-stakeholders where the interests and problems of resource poor farmers are included and central to the R&D agenda. In addiction, the scientification is challenged by the relative low technical requirements to produce the Bt spray. Finally, the *remote control* is broken by the dynamics and new partnerships in which scientists, farmers, civil society organizations and villagers communicate with each other and cooperate in the management of the local available resources.

Therefore, the adaptation of the production of the Bt-spray to the local circumstances not only represents the appearance of a new product, but also the emergence of new social relations. These new social relations are breaking through the (already) traditional dependence of farmers on external institutions.

During the redesigning process of the bio-pesticide, the self-organising dynamics engaged by the network has provoked a shift in the power relations that traditionally are structured around the development of biotechnology products. Therefore, new identities have been adopted by the different actors, like social researchers of the BTU who became key actors by linking scientists, NGOs and farmers during negotiations around biotech developments, or scientists that are forced to abandon their ("ivory tower") labs in town to come closer to the potentials and constrains of rural India. Accordingly, the Bt-product has acquired new politicizing dimensions that push the network to reproduce local appropriate developments. This becomes visible by the further local deployment of the technology across the decentralised mass multiplication centres at the village level. In these centres, again new political roles are assumed. This time in the form of NGOs members who become biotech producers.

Concluding, the Bt-spray is political in the sense that its emergence brings about the appearance of new social dynamics that not only creates material goods but also inclusive relationships and ultimately reorganises social life itself.

Placing the Scope of the Social Relations Shifts in Perspective

Before we go further with the final discussion, two bottlenecks concerning the political control exercised by the biotech network can be mentioned.

David Noble (1977), when discussing the centrality of claims for radical changes about to come with technological transformations, has noted that despite the promises of revolutionary changes, the old order reproduces itself, 'a change without change'.[59] Although these words of Noble are quite pessimistic in general and may deny social change or human agency, they are in a certain way true. As far as our case is concerned, the hierarchic Indian social structure goes on in reproducing itself by supporting the old elites, like scientists (some of them don't feel like belonging to the Bt network, but to the one of their urban institutes) or creating new ones, for instance, the empowered NGOs that can create new clientelist relations with farmers' communities by acquiring the control on the Bt production centres.

Another important issue for the sustainability of the Bt network is the financial support of the APNLBP by the Dutch ministry of foreign affairs. Further studies of this biotech network should be done to find out whether this unique economic financial source and dependence may become a bottleneck for the different projects (and therefore, for the Bt-spray).[70] However, by the local reorganization of the production of the bio-pesticide this economic dependence can be overcome because of the autonomy earned by the Bt network in the form of Bt multiplication centres.

Discussion

Is the APNLBP Bt-spray a new pest-management product? If we just look at the final product the answer will be simply no; it is just a bio-pesticide on the basis of Bt which is sprayed in farmers' fields. But if we analyse the new social code attached to the redesigned product we are able to appreciate the qualitative differences that make the new pest management product indeed a suitable alternative for small scale agriculture in Andhra Pradesh. To reach this position, the techniques are designed to facilitate an organization of the Bt production process based on primarily (though not exclusively) locally available resources. The political management on the Bt technology development has been reorganized towards an increased involvement of multi-stakeholders platforms in the design, production and deployment of the new Bt products. Finally, the benefits and responsibilities have been redistributed within the region where the biotechnology development is taking place. Thereforem, new identities have been and are shaped (like NGOs that became producers of biotech products, or social scientists that get involved in the coordination of biotechnology programmes) that are transforming the traditional Indian structures of biotechnology development.

However, some friction still remains between the present Indian landscape concerning biotechnology development and the moral dimensions of the Bt-spray product. For instance, of the problems and limitations can be perceived is that the largest, but culturally and economically marginalized stratum of the society, the resource poor farmers, have to gain access to the discussions around biotechnology (e.g. knowledge asymmetries, NGOs mediation roles, etc.).

Moreover, the objectives of the Bt-spray project are not only the development of a cost-effective pest-management technique but also rural development. Therefore, from a social science perspective, it could be helpful to understand that between technology and society there is a deeply mutual interaction or a co-construction.[71] In fact, technology is one more of the politic arenas in which society is constructed.[72] Consequently, it is necessary to recognise the rights that larger sectors of the population have to gain control on technological developments that are affecting their daily lives; like farmers on the production of (bio) technologies that for good or bad are shaping rural life. It is not only morally appropriated to incorporate farmers in those developments but it could also be more efficient.

Traditionally, an external control on the development of pest-management techniques has been framed within, what some scholars have called the modernization or industrialization process of agriculture. That was assumed to be unilinear and encouraged farmers to become more integrated in markets and dependent on the use of external inputs, technologies and capital.[73] It promoted a more uniform pattern of farming. As such it resulted in a weakening of the linkages between farming and local ecology[74] and was, therefore, devaluating the informal farmers' knowledge.[75] While the tendency was to look at innovation primarily as a process of 'scientific research', scholars now tend to look at it as a process of 'network building',[76] 'alignment', 'social learning' and 'negotiation.'[77] In addition, as Latour has alleged, scientific research is conducted less and less in autonomous institutions of pure research or vast centralized public facilities, and more and more in collaborative networks which cut across the distinctions between the pure and the applied, the public and the private, the academic and the commercial.

Moreover, the unidimensionality of biotechnology developments has been abandoned and replaced by the notion of co-construction of various technical and social arrangements within a concrete reality. Analysis of the redesigning of our bio-pesticide takes place within this dialogue between the material and social elements. Therefore, since it is accepted that a variety of relevant social groups are involved in the social construction of technologies and that the co-construction process between society and technology continues through all phases of an artefact's life, it makes sense to extend in a timeless continuum the set of groups involved in political deliberation about technological choices.[78] Therefore, it becomes desirable to extend the pluriform participation also to the deployment phase, and to the daily use of the technology to asses its performance. This is the way in which the emerging *bioresource-centres* in the rural landscape of AP may play an interesting role by acting as the catalyst for local development through a politically conscious construction and reconstruction of biotechnologies.

In conclusion, by the local management of the available human and natural resources and the subsequent redistribution of the benefits and responsibilities coming out of the development of the Bt-product, the new bio-pesticide has acquired a politic and politicising character that encourage the reproduction of the social structures, roles and identities organised around it to guaranttee the sustainability of the biotechnological rural developmental process. Future studies on the topic will address whether the exposed biotechnological developments engaged by the local agents gain momentum and whether those dynamics indeed work as a catalyst for local development in Mahaboobnagar and Nalgonda.

Endnotes

[1] In this paper, biotechnology is understood as "any technological application that uses biological systems, living products or processes for specific purposes". This is the definition given to biotechnology at the 1992 Rio Convention of Biological Diversity. Quoted in: (Adler 2000: 175). Therefore, in this article biotechnology means both fermentation processes and the last applications of genomics.

[2] Some of these experiences are organised around the international Tailor Made BioTechnology Network

[3] The Dutch Ministry of Foreign Affairs, across its development-cooperation agency (DEGIS), has launched a special programme on biotechnology to improve the quality of life of resource poor farmers in two predominantly dry land districts , Mahaboobnagar and Nalgonda in Andhra Pradesh (which is one of the federal states of India). The Programme is implemented in the name of "The Andhra Pradesh Netherlands Biotechnology Program for Dryland Agriculture" (APNLBP). The APNLBP use a methodology where the biotech projects are based on local needs assessment and priority setting. The network is formed by farmers, NGOs, policy makers and scientists (see figure 1). Very recently, APNLBP has changed its name to Agri Biotech Foundation (ABF). The Dutch Government has provided the necessary financial support, while the local Agricultural University has provided land to build ABF's own campus (June 2, 2007). The mandate of the Programme has been expanded to other states of India as well as to other

developing countries. For more information see: www.abfindia.org (G. Pakki Reddy – ABF's executive director – personal communication August 6, 2007)

[4] The use of bio-pesticides is one of the alternatives employed worldwide for pest management. Bio-pesticides make use of naturally occurring pest killers (fungi, bacteria and nematodes). One of the bio-pesticides with larger use is the soil bacteria Bacillus thuringiensis.

[5] www.worldbank.org/in

[6] Castor is one of the major oilseed crops of India accounting for 76% of the world exports. Within India, Andhra Pradesh is one of the major castor growing states (0.39 million ha.) with an annual production of 0.13 million tonnes (DOR 2003).

[7] Gaikwad & Bilapate (1992); DOR (2005).

[8] Unlicensed dealers and retailers sell pesticides without being aware of their toxicity. This uncontrolled marketing has escalated pesticide misuse. In addition, from time to time 'ghost companies' come to the villages to sell pest-management products that vary from out of date pesticides, to just water in pesticide package. Furthermore, banned pesticides like DDT and BHC are still being sold on these regions. This could mean that the actual pesticide consumption is higher than the available official figures (Shetty 2004).

[9] Vimala Devi & Rao (2005a).

[10] Kolanu & Kumar (2007).

[11] Reddy (2003).

[12] Among those Monocrotophos 0.05%, quilalphos 0.05%, endosulfan 0.07% and acephate 0.075% are reported to be efficient against the semilooper (DOR 2003; 2005). But they are also reported to be highly toxic for human health and other organisms (Shetty 2004).

[13] DOR (2005).

[14] Vimala Devi, Prasad et al. (1996).

[15] Kough (2003).

[16] Vimala Devi, Ravinder et al. (2005).

[17] Krattiger (1997).

[18] Vimala Devi, Ravinder et al. (2005).

[19] Kleinman (2005).

[20] In 1995 the US Environmental Protection Agency approved the commercial release of the first transgenic crop containing a pesticide in the form of a Bt-potato to control the Colorado potato beetle (Krimsky & Wrubel 1996; Kleinman 2005).

[21] Krimsky & Wrubel (1996); Jenkins (1998); Kleinman (2005)

[22] Jenkins (1998).

[23] AgrEvo and Rhône-Poulenc Agro formed in 2000 Aventis CropScience which in 2002 was bought by Bayer forming Bayer CropScience (info available at www.bayercropscience.com).

[24] Qayum & Sakkhari (2005).

[25] The most illustrative example is the massive suicide of farmers because of the debts gained by the purchasing of the transgenic cotton seeds provided by Mayco-Monsanto in the Warandal District in Andhra Pradesh (Shiva & Jafri 1998; Stone 2002).

[26] APNLBP is also developing a transgenic castor variety to manage the castor-semilooper: Bt-castor. Although the Bt-castor has already been developed in the

lab, the bottleneck in this project is the absence of a deployment strategy for the Bt-crop for the poor regions. Also a question of feasibility remains: where will the Bt-castor seeds be produced? What will be the price of those seeds? How will the Bt-castor deal with the negative image that some farmers and especially local NGOs have regarding transgenics?

[27] In India, Bt based pesticides are being marketed by three companies. The total sale in 1999 was about 70 tonness (Dr MC Sharma, pers. Comm.. Director, Biotech International, New Delhi)

[28] In this context, efficiency means: longer shelf life, ease of application and enhanced performance of Bt formulations (Brar, Verma et al. 2006)

[29] The basic active agent of Bt, called delta endotoxin, is produced in the form of crystalline parasporals inclusions during the sporulation. According to Rowe and Margaritis (1987) and WHO (WHO 1999), nine different toxins have been described in Bt strains. Of those toxins, the delta endotoxin have received much attention in the production of bio-pesticides (El-Bendary 2006)

[30] Vimala Devi & Rao (2005b).

[31] Vimala Devi & Rao (2005b); El-Bendary (2006).

[32] El-Bendary (2006).

[33] ibid

[34] ibid

[35] Vimala Devi & Rao (2005b).

[36] Vimala Devi & Rao (2005b); El-Bendary (2006).

[37] El-Bendary (2006).

[38] Actually, APNLBP is coordinating about 65 different projects.

[39] Here we want to put the quality of this knowledge exchange in perspective. For instance, some communication problems were caused because some city-scientists were unfamiliar with the local rural-languages. This forced us to hold some of the meetings in a different language than the language used by local farmers.

[40] From these five, two Bt kurstaki strains (4D17 and 4D21) were found effective against the castor semilooper, Achoea janata. These two were used for the study in addition to four local isolates of Bt from the farmers fields.

[41] DOR-1 contains the cry genes: cry 1Ab, cry 1Ac, cry 2Ac, cry 2Ab, cry 1.

[42] Vimala Devi & Rao (2005b). The cost benefit ratio for DOR Bt-1 treatment (2 sprays) was 3.10 while it was 1.62-1.80 in quinalphos – 5 sprays (Ekalux EC 25) (Vimala Devi & Rao 2005a).

[43] They are able to do it by checking the hardness of the dead larva.

[44] Nevertheless, we have to recognize the difficulty for farmers and lay persons in general to be able to understand technological discussions. Here, we are confronted for instance with problems such as the local educational systems that are beyond the scope of this article.

[45] Vimala Devi & Rao (2005b).

[46] ibid

[47] There are some researchers that have pointed out that this use of high and low biotechnologies is part of a "short and long term perspective"; the short term perspective focus on low-tech and the long term on high-tech (Clark, Yoganand et al. 2002). Although this is indeed the official intentions of the APNLBP, in my view this network is in practice developing an integral biotechnological approach where all the biotechnological choices are considered in the struggle of poverty alleviation. This point is illustrated by the case analyzed on this article.

[48] Vimala Devi & Rao (2005b,113)

[49] About 150 grams of Bt powder are used to spray one acre (2.5 acres =1 Hectare).

[50] For instance, some of them even don't know how much will be the price of the final product.

[51] Ghose & Ghosh (2003).

[52] The IBU was named so deliberately to show the contrast with 'the 'top-down model' of external development of biotechnology (Bunders 1990; Broerse & Bunders 2005).

[53] This scheme was inspired by (Buijs 2002)

[54] The most basic control, one can think of, regards the quality and price. If the product is too expensive and not effective, farmers will simply not buy it.

[55] Rajeswari (1999); Clark, Yoganand et al. (2002); Sualiman & Hall (2002).

[56] Damodaran (2004).

[57] Pingali & Traxler (2002); Broerse & Bunders (2005).

[58] Clark, Yoganand et al. (2002).

[59] Bioserve (Lead by Bioserve USA) and Bangalore Genei (owned by the Indian chemical corporation "Sarman Group")

[60] www.worldbank.org.in (09-05-2006)

[61] Humphries, Gallardo et al. (2005).

[62] Clark, Yoganand et al. (2002).

[63] At this stage we could speak of the subpolitical (Beck 1997) character of the local networks because it mobilises resources and organise politics beyond the representative institutions of the political system of the Indian nation-state.

[64] Ruivenkamp (2003a); Kloppenburg (2004)

[65] Goodman, Sorj et al. (1987).

[66] Ploeg & Frouws (1999).

[67] Ruivenkamp (1989; 2003a) has analysed, how through the development of tissue culture or r-DNA techniques, seeds companies are becoming increasingly able to intervene more radically and efficiently in the genetic structure of plants and to determine where, when and how a crop should be sown, (with or without herbicides) harvested and processed. And it is precisely through the supply of these new seeds with specific properties that the companies can 'program the agricultural production from a distance'(ibid.2005a; p. 14)

[68] Ruivenkamp (1987; 2005a).

[69] (ibid.; p. xxiii)

[70] The APNLBP is one of the four country programme supported by the Dutch Ministry of Foreign Affairs. The other three country programmes were in operation in Colombia, Kenya and Zimbabwe. In the last two countries, the economic support has stopped, what has meant the end of the local projects.

[71] Misa (2003).

[72] Feenberg (1995); Sclove (1995); Feenberg (1999); Ruivenkamp (2005a; 2005b); Bijker (2006).

[73] Toledo (1990); Ploeg & Frouws (1999); Ruivenkamp (2005b; 2005a).

[74] Renting & Ploeg (2001).

[75] Ploeg (1991); Ruivenkamp (2003b).

[76] Callon & Law (1986).

[77] Leeuwis & Remmers (1999).

[78] Bijker (2006).

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Reorientation of Agricultural Research for Addressing Food Security Issues through Agricultural Biotechnology

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Abstract: R&D capacity is an important factor in harnessing new technological pathways for increasing agricultural productivity, building food security and contributing towards economic stability of agriculture-based economies, like India. Agricultural R&D in India gives high priority to application of biotechnology to evolve new genetically engineered strains of plants, resistance to pest and diseases, animals and fishes of high nutritional quality, and attaining environment-friendly farm practices. The success of such technological intervention will largely depend on a re-furbished and reoriented agricultural research system which is efficient and cost effective and which addresses the problems of marginal environments and interests of small and marginal farmers who dominate Indian agriculture. This paper argues for the need for reorientation of agricultural research for harnessing the potential of biotechnology in agriculture. Since biotechnology research is complex and highly capital intensive, the research system should allocate scarce capital resources optimally so as to ensure research efficiency and restrain a thin spread of resources. This can be achieved by prioritisation of biotechnology research and development and delivery of such agricultural biotech products which contribute to food security. Therefore, proper research planning, prioritization of agricultural biotechnology research and an effective policy framework are the essential components of utilization of agricultural biotechnology in a way that contributes towards food and nutritional security in India.

Keywords: Biotechnology, agricultural R&D, research planning, research prioritization, food security, GE plants

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Background

Today, the world is driven by science and technology (S&T) as radical changes are taking place in all spheres of technology. The Indian agriculture sector too has seen major technological changes during the last four decades. The introduction of high-yielding varieties (HYVs) in the late 1960s led to a large increase in agricultural productivity and food production. This technology-led green revolution (GR) brought HYVs of wheat and rice varieties, developed with conventional breeding methods, to millions of small-scale farmers in Asia and Latin America and later in Africa as well. The yield of major food crops, particularly rice and wheat, more than doubled between 1960s and 1990s and India achieved self-sufficiency in food grains at the national level. But, the areas which experienced GR are facing second generation problems of soil-salinization, ground-water pollution, nutrient imbalances, emergence of new insects and diseases and environmental degradation.[1] The plateauing of yield of major food crops in recent years and loss of biodiversity has also added another dimension to the problems of Indian agriculture. Moreover, by 2020, India's population is likely to be around 1.3 billion and the country's overall employment scenario is less likely to change significantly.[2] An estimated 340 million people in India are very poor and chronically undernourished. The opportunities for area expansion being almost limited, an additional food output of 4-5 million tonnes per annum will have to come primarily through increased agricultural productivity.

Agricultural R&D capacity is an important factor in using new pathways for increasing agricultural productivity, achieving food security and contributing towards economic stability of agriculture-based economies, like India. Therefore, a well-developed agricultural research system is one of the important pre-requisites for a proper utilization of the cutting-edge and better-targeted technologies and for their effective adoption and dissemination along with the conventional methods of production. Accordingly, agricultural R&D in India gives high priority to application of biotechnology to evolve new genetically engineered strains of plants, resistance to pest and diseases, animals and fishes of high nutritional quality, and attaining environment-friendly farm practices.[3] In the interest of reaching the poor and the population in marginal environments, vigorous extension efforts should continue for maximum uptake of technologies on self. Unfortunately, our extension approaches and system are failing in this direction. But efforts should continue to make breakthroughs in science by application of biotechnological and other advanced scientific tools.

This paper takes stock of the status and focus of agri biotech research and assesses the essential ingredients for research planning and the policy framework for utilization of agricultural biotechnology in a way that contributes towards food security. The success of such technological intervention largely hinges upon a re-furbished and reoriented agricultural research system which is efficient and cost effective in utilizing the cutting-edge technologies for the betterment of vulnerable sections of society and which addresses the problems of marginal environments. Focusing our research efforts towards enhancing the nutritional attributes of cereals and pulses and tackling biotic and abiotic stresses of these crops will particularly help in addressing the issue of food security.

Funding Support

Many Asian governments –including China, India, Indonesia, Malaysia, Philippines, Thailand and Vietnam have given high priority to plant biotechnology research in the hope of addressing the pressing challenges related to improving productivity, farmers' livelihoods, driving rural development and meeting food security demands.[4] The Indian government's spending for research projects related to biotechnology also increased significantly during the last few years. During the Ninth Five Year Plan, the government provided budgetary support for biotechnology to the tune of Rs.6690 million. This has substantially been increased to Rs.14500 million (116.7 per cent increase) in the Tenth Five Year Plan (2002-2007). In fact, the Government of India is proactively introducing sustained funding and fiscal initiatives to facilitate the growth of its biotech sector. For example, the Department of Biotechnology's budget increased from approximately $30 million in 1999 to nearly $120 million in 2005. The government has promised to nearly double its science budget from 1.1 per cent of its gross domestic product in 2005 to 2 per cent by 2007.[5]

Nonetheless, public biotechnology investments in India still appear to be quite small compared to the size of the country and the urgent need for innovative and sustainable agricultural technologies. A comparative view of R&D investment in India *vis-à-vis* that in some major countries indicates that our investment on R&D in agriculture is only 0.48 per cent of Ag GDP as compared to developed countries like

Australia (4 per cent) and around 3 per cent in the US, UK and Japan. We have also less scientists (158) per million of population as well as expenditure per scientist (US $ 17.5 thousand) as compared to developed countries like the US (4103, US $ 213 thousand), Japan (4960, US $ 203 thousand). Even China (459, US $18.5) is far ahead of India on these counts (see Table 1). In the private sector the level of R&D activity is substantially higher. For example, the R&D expenses of Monsanto Inc. alone accounted for 11 per cent of sales for the fiscal year 2004.

Table 1: Support to R&D by Public Sector in Different Countries

Country	Agri. Share (%) in GDP	People dependent on agriculture (%)	Public expenditure on Agri. R&D (% of Ag GDP)	Scientists per million of population	Expenditure per scientist ('000 US $)
USA	0.7	1.6	2.80	4103	213
Japan	2.3	2.9	2.80	4960	203
UK	1.8	1.5	2.89	2678	164
Australia	3.1	4.8	4.02	3320	101
China	15.2	59.8	0.43	459	18.5
India	26.3	63.2	0.48	158	17.5

Source: World Bank (2001).

Institutional Focus

Different public and private agencies in India are engaged in modern biology research. These include the Council of Scientific and Industrial Research (CSIR), the Indian Council for Agricultural Research (ICAR), the Indian Council of Medical Research (ICMR), the Department of Science and Technology. However, biotechnology received a boost in 1982 with the establishment of National Biotechnology Board (NBB) within the Department of Science and Technology. Its initial impact prompted the government to establish a separate Department of Biotechnology (DBT) under the Ministry of Science and Technology in February 1986. At this stage, its mandate was broadened to include the promotion of large-scale use of biotechnology, the support of university and industry interaction and the development of biosafety guidelines, among others. There have been major accomplishments in areas of basic and applied research in agriculture, health, environment, human resource development, industry, safety and ethical issues.[6] A great part of the agricultural biotechnology research in India is carried out in laboratories that already existed before the founding of DBT. Many of these are supported and coordinated by ICAR. In total, there are about 56 public research units in India using tools of modern biotechnology for crop improvement.[7] Out of these, more than ten are engaged in plant genetic engineering, with rice, chickpea, different oilseeds, cotton and a number of horticultural species being the main target crops. Apart from national institutes, an Indian branch of the International Center for Genetic Engineering and Biotechnology (ICGEB) was established in late 1980s in New Delhi. Furthermore, there are about 50 private companies (domestic and foreign) engaged in agricultural biotechnology research in India.

While the public sector played a strong role in R&D and technology diffusion during Green Revolution periods, the majority of agricultural biotechnology research and its commercialization is taking place in private firms based in industrialized countries. The moot question is whether farmers in developing countries, particularly poor farmers, will benefit from appropriate biotech innovations or these would be beyond their reach in economic terms. Therefore, the R&D in agricultural biotechnology has to re-orient itself to allay such concerns which prove a deterrent to fast track development and application of agricultural biotechnology.

In India, initially the focus in the 1980s was on institution building and capacity development followed by specific, problem-oriented R&D efforts in the 1990s. However, in general, it must be stated that India lacks hard-core agricultural biotechnology research and we are still on the periphery of recent advances which are propelling biotechnology research in this century. In fact, there is a dearth of human resources trained and skilled in use and application of modern biotechnology methods particularly in agriculture. Fully realizing this, the ICAR has provided to young scientists advanced training in biotechnology abroad under the National Agricultural Technology Project (NATP). Such capacity building efforts are necessary to develop a critical mass in frontier areas of technology.

Need for Research Reorientation

Re-orienting our research efforts towards, productivity enhancement, loss minimization, post-harvest management and value addition will be critical for ensuring sustainability and increasing farm incomes and profitability. A number of transgenic R&D activities, at different stages of development, are in the pipeline in India which are likely to produce technology products over the short to medium term (see Table 2). It can be seen from the table that field experiments have already been carried out with six different crop species, mostly vegetables.

The ICAR is also giving due attention to application of biotechnology for crop protection and improvement. Current research efforts, among others, include development of transgenic tomato resistant to tomato spotted wilt tospo virus, the study of molecular events during fruit ripening in banana and mango in order to decide the right strategy for genetic manipulation of these crops for delayed ripening, and developing strategies for micro-propagation in mango through nuclear embryo-genesis. Since the tomato spotted wilt virus (TSWV) cannot be controlled by chemical means or other conventional methods, development of transgenic lines of tomato resistant to the virus is considered a viable approach. Further, post harvest losses in

Table 2: Focus of Transgenic Research in India, 1994-2004

Crop	Trait	Status
Mustard	Herbicide tolerance (*bar, barnase, barstar*)	Field trials
Tomato	Insect resistance (Bt), delayed ripening	Field trials, Experimental phase
Eggplant	Insect resistance (Bt)	Field trials
Brinjal	Insect resistance (Bt)	Field trials
Tobacco	Insect resistance (Bt)	Field trials
Aflatoxin producing fungi	Monoclonal antibodies	Experimental phase
Brassica	Moisture stress	Field trial
Cabbage	Lepidoptera	Experimental phase
Cardammon	Micropropagation	Experimental phase
Coffee	Micropropagation	Experimental phase
Cotton	Gene cry1Ac Cultivars	Commercialized
Cut flowers, Mango	Micropropagation	Experimental phase
Potato	Starch composition	Experimental phase
Potato	Vitamin content (AmA1 gene)	Experimental phase
Rice	Virus and fungi resistance, gene cloning, salt tolerance	Experimental phase
Wheat	Protein content, grain size, microsatellite markers and cold tolerance	Experimental phase

Source: Qaim (2001) and www.fao.org.biotech/inventory admin/dep/stat result.asp?country=IND tropical fruits like banana and mango due to low shelf life are quite significant. Studies are in progress focusing on enzyme activities and their regulation by ethylene during fruit ripening, differential expression of ripening-related genes.

These research efforts have generated some intermediate research products. For example, transgenic tomato with resistance to tomato spotted wilt virus, will greatly help in reducing the yield loss caused by this disease which is between 20 to 90 per cent depending on the stage of the crop. Strategy to increase the shelf-life of mango and banana will lead to minimizing post harvest losses which can be to the extent of 40 per cent in these two important horticultural crops. The complete protocol for micropropagation of mango will be helpful in making available large numbers of elite planting material as well as pave the way for genetic transformation of mango with traits of importance, like increased disease resistance and increased shelf life. However, it is difficult to estimate the overall impact of these technologies at this juncture.

The external R&D funding has contributed significantly for strengthening and promoting biotechnological approaches for the improvement of horticultural crops. Since application of biotechnology is a costly proposition, the external R&D support to ICAR has enhanced the skills of research staff and therefore, enhanced the pace and efficiency of research.[8] To meet the challenges of globalization and to harness the potential of upcoming technologies, the ICAR has outlined the roadmap for biotechnology research for the coming years. A gist of the reoriented research focus relating to crop production, crop protection and crop improvement is provided in Table 3.

Since biotechnology research is characterized as complex and high capital intensive, the research system should allocate the scarce capital resources optimally so as to ensure research efficiency and restrain a thin spread of resources. This can be achieved by prioritization of biotechnology research keeping in view the national and regional goals. For example, the Analytical Hierarchy Process (AHP) can be used to prioritize the research projects on biotechnology. The AHP is a decision support tool to tackle complex multi-criteria problems such as assessing research priorities. The method helps to structure and analyse decision problems by breaking down the complex problem in a hierarchic order, and employing pair wise comparisons of its elements to determine the preferences among the set of alternatives.[9] Joshi, *et al.* (2002) used this process to establish an objective criteria for ranking the biotechnology

Table 3: ICAR Road Map for Biotechnology Research on Crop Production and Crop Protection

Thematic area	Research focus
Crop improvement	• Identification of sources of resistance to biotic and abiotic stresses • Quality traits in crop plants for diversified utilization • Molecular mapping and integrated gene management • Commercially viable varieties of commercial crops - high sugar content, improved fibre quality and capable of diversified uses • Gene pyramiding for biotic and abiotic stresses. • Precision agriculture and integrated farming
Crop production technologies	• Integrated plant nutrient management and genetic analysis of responses in relation to nutrient uptake efficiency under both stress and non-stress environments
Crop protection technologies	• Studies on plant-based agro chemicals/ biopesticides • Herbicidal chemicals, IPM

Source: Compiled from various sources of ICAR.

research proposals for ranking research priorities for future research funding in a resource-crunch scenario. The analysis revealed that priority scores of all the projects were quite high indicating their relevance at the national and regional level (Table 4). The ranking of the projects based upon objective criteria show how incremental research resources should be allocated. Out of the ten research projects, three projects addressing submergence tolerance and cold tolerance in rice and salt tolerance in brassica were among the top three research priorities for allocating the research resources. At the

Table 4: Indices of Different Indicators Expected from each Research Project

Project	Criteria						
	Economic	Trade	Equity	Environ mental impact	Social impact	Success of research	Success of adoption
Cold tolerant lines in rice	4.69	0.27	0.41	0.62	0.37	0.68	1.58
Submergence tolerance in rice	4.67	0.73	0.14	0.51	0.03	0.43	0.73
Expression of genes in B. juncea for salt tolerance	2.09	0.59	0.23	0.16	0.00	0.54	2.30

Source: Joshi, *et al.* (2002).

same time, the broader issue of acceptance/rejection of biotechnology in the changing social milieu could well be addressed by more socio-economic studies on the public perception of GM foods in India and their risk and cost-benefit analysis which should be undertaken concurrently with all the biotechnology research programmes.

Policy Environment

A flavour of biotechnology policy objective is imparted by the Vision Statement of DBT which reads as "attaining new heights in biotechnology research, shaping biotechnology into a premier precision tool of the future for creation of wealth and ensuring social justice - specially for the welfare of the poor". States like Andhra Pradesh, Maharashtra, Karnataka, Punjab and Tamil Nadu have formulated their state biotechnology policies for giving a boost to biotechnology R&D. Notwithstanding these initiatives in pockets, efforts are still on for developing a biotechnology policy at the national level for fully utilizing its potential in priority research areas.

The time is ripe to work out clearly the essential elements of agricultural biotechnology policy. One simple thumb rule can be applied that it should primarily accelerate development process. Unfortunately, most often we talk in generic terms and loose real focus where our research efforts should be directed for making agricultural biotechnology work for the poor. At the same time, we should have a realistic assessment of comparative advantages of both public and private sector. Private sector operates at cutting edge level, makes speedy decisions and have professional work culture which is essential for utilizing the fast changing dynamics of this technology. However, the private sector hesitates to make huge investments due to some grey areas concerning the protection of intellectual property rights (IPRs).

Notably, the emerging IPR issues have started influencing the quality of agricultural research carried out and the nature of research collaborations between the public and private sector and between developing and developed countries. In the ultimate analysis, it is the scope of patentability, protection of 'enabling technologies' and the multiplicity of patents required to develop an agricultural product and structure of agricultural industry (public/private concentration) which would determine the impact of IPRs system on research investments in agricultural biotechnology. The national biotechnology policy should address these issues in a transparent and unambiguous manner.

Summing up

Today, the world is driven by S&T and radical changes are taking place in all spheres of technology. In case of Indian agriculture too though the rate of technical change has not declined (due mainly to the continuous R&D efforts), it is certainly decelerating in recent times. Therefore, the business as usual approach is not going to help in the present context. A complete re-orientation of the research system is called for which can fully utilise the potentials of frontier technologies like agricultural biotechnology. This needs to be complemented by an enabling policy environment and effective implementation of research goals. The socio-economic policy instruments should be designed to take care of the poverty, equity and sustainability implications of emerging technologies.

Biotechnology application in agriculture has opened new vistas for tackling production and post-harvest operations which in turn can contribute towards food security. But we are still working on the periphery of agribioteh research issues and our impact factor is insignificant. There are a lot of scale as well as skill problems. In reality, we don't have real biotechnologists who are skilled enough to harness the potential of cutting-edge technologies. Since, biotechnology research is characterized as complex and high capital intensive, the research system should allocate scarce capital resources optimally so as to ensure research efficiency and restrain a thin spread of resources. This can be achieved by prioritization of biotechnology research keeping in view the national and regional goals. The government may consider identifying a few priority research areas, and create a dedicated fund for the development and delivery of such agricultural products which contribute to food security. However, to figure on the global biotechnology map, we need substantial resources for capacity building, institutional infrastructure and effective policy implementation.

Endnotes

[1] ICAR (2000).

[2] ibid

[3] ibid

[4] Hautea and Escaler (2004).

[5] Dhawan, et al. (2005); Mayor, (2005).

[6] Sharma (2000).

[7] www.biotechsupportindia.com

[8] Mruthyunjaya, et. al. (2004).

[9] Saaty (1980); Braunschweig (2000).

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Document

Providing Biotechnology Statistics and Indicators to the OECD Biotechnology Statistics 2008*

The OECD has been collecting and publishing data on biotechnology from its Member and several non-member countries since the 2001 Biotechnology Compendium. The most recent publication is the *OECD Biotechnology Statistics 2006,*[1] which includes more internationally comparable indicators than the 2001 Compendium. The OECD is planning to produce its next collection of biotechnology statistics in 2008 and hopes to further improve international comparability. This involves increasing the number of countries that provide comparable data for specific indicators and the absolute number of comparable indicators.

The *Biotechnology Statistics 2006* report includes data for three non OECD countries: Israel, South Africa and the Shanghai province of China. For the 2008 edition, the OECD would like to include comparable data on biotechnology statistics for a larger number of non OECD countries, or, if necessary, for regions or provinces within large countries such as China, India, or Brazil.

This brief report explains the approach of the OECD to producing internationally comparable biotechnology statistics. This information should be helpful for countries that would like to provide indicators for inclusion in the 2008 edition of *Biotechnology Statistics.*

Relevant Data

The *Biotechnology Statistics* reports include three types of data:

1. Biotechnology activities of the public sector, particularly investment in biotechnology R&D.
2. Biotechnology activities of the business sector.

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3. Methodology of data collection (metadata).

The information needed by the OECD for each type of data is given below in Sections 2, 3 and 4. A country only needs to provide a few internationally comparable indicators and the supporting metadata to be included in the 2008 Biotechnology Statistics.

Definition of Biotechnology used by the OECD

International comparability is strongly dependent on how biotechnology is defined. The OECD limits biotechnology indicators to modern biotechnologies. This excludes the traditional fermentation of soy, dairy and alcohol products. Conventional plant and animal breeding are also excluded, unless biotechnologies such as marker assisted selection (MAS) are used as part of the conventional breeding programme.

To maximise comparability of both the public and business sector biotechnology statistics, countries should use the OECD single definition of biotechnology and the list-based definition (see Box 1 below) of different types of biotechnology. Both definitions were developed by an OECD expert group. The first defines biotechnology as, *"the application of science and technology to living organisms, as well as parts, products and models thereof, to alter living or non-living materials for the production of knowledge, goods and services."* Although the single definition defines the purpose of biotechnology, the list-based definition is essential for identifying modern biotechnology.

In the *Biotechnology Statistics 2006* report, the OECD includes data for a few countries that used a different definition of biotechnology, as long as the definition was limited to 'modern' biotechnology. This option will still be available in 2008, although we encourage countries to adopt the OECD definition.

Reference Year

The OECD prefers to have data for the most recent available year, which is 2006 or 2007 for the 2008 report. However, the report will include data for 2004 or 2005, if no data are available for 2006 or 2007.

Application Field

Where possible, the OECD provides biotechnology statistics for up to four major applications of biotechnology: in the following sectors namely health, agriculture (including food processing and marine uses

BOX 1: OECD list-based definition of biotechnology techniques

DNA/RNA: Genomics, pharmacogenomics, gene probes, genetic engineering, DNA/RNA sequencing/synthesis/amplification, gene expression profiling, and use of antisense technology.

Proteins and other molecules: Sequencing/synthesis/engineering of proteins and peptides (including large molecule hormones); improved delivery methods for large molecule drugs; proteomics, protein isolation and purification, signaling, identification of cell receptors.

Cell and tissue culture and engineering: Cell/tissue culture, tissue engineering (including tissue scaffolds and biomedical engineering), cellular fusion, vaccine/immune stimulants, embryo manipulation.

Process biotechnology techniques: Fermentation using bioreactors, bioprocessing, bioleaching, biopulping, biobleaching, biodesulphurisation, bioremediation, biofiltration and phytoremediation.

Gene and RNA vectors: Gene therapy, viral vectors.

Bioinformatics: Construction of databases on genomes, protein sequences; modelling complex biological processes, including systems biology.

Nanobiotechnology: Applies the tools and processes of nano/microfabrication to build devices for studying biosystems and applications in drug delivery, diagnostics, etc.

such as aquaculture), industrial, and environmental. Data by application has many advantages in terms of predicting the future direction of biotechnology, improving the comparability of output indicators,[2] and estimating social and economic impacts, which are strongly dependent on the application.

Public Sector Investment in Biotechnology R&D

Optimally, the OECD would like to publish data on total government expenditures on biotechnology R&D, plus expenditure data broken down by application field and by the recipient of the funding. The template for 'Public Biotechnology R&D' is provided as an example of how to obtain the basic data from government ministries.[3] The following indicators for a specific year can be produced using the information collected in the template:

1. Total public expenditures on biotechnology R&D.
2. Total public expenditures on biotechnology R&D by field of application.
3. *Alternative if a breakdown by application is not available*: Share of all Government programmes for biotechnology R&D by application field.
4. Total public expenditures on biotechnology R&D by type of recipient.
5. *Alternative if a breakdown by recipient is not available*: Share of all government programmes for biotechnology R&D by recipient.

Section 4 below lists four metadata items that are required for public R&D data.

Public Biotechnology R&D Template

Please list publicly funded biotechnology R&D programmes that exist in your country in the table below. For each programme, please provide as much of the information below as possible. Please use a separate template for each programme that funds biotechnology R&D.

1. Basic information		
Name of programme		
Responsible government ministry		
Is this programme dedicated to funding biotech R&D?	Yes ☐	No ☐
Or, any other programme that also funds biotech R&D?	Yes ☐	No ☐
Duration of programme (number of years)	_____ Start year _____ End year	
Total amount of funding for biotech R&D (*exclude non biotech R&D*) over the lifetime of the programme	____________ (National currency)	

2. Distribution of programme funding for biotechnology R&D by application field

Type of biotech R&D funded:	Check all that received funding:	Estimated share of total funding of biotech R&D *(Exclude non biotech R&D from total)*
Health (human and animal)	☐	______
Agriculture-marine-food processing	☐	______
Industrial	☐	______
Environmental	☐	______
Other (please describe):	☐	______
		100%

3. Distribution of programme funding for biotechnology R&D by sector of recipient

Recipients of biotech R&D funds:	Check all that received funding:	Estimated share of total funding of biotech R&D *(Exclude non biotech R&D from total)*
Business	☐	______
Higher education	☐	______
Government research organisations	☐	______
Private non-profit	☐	______
		100%

2. Biotechnology Activities of the Business Sector

The OECD *Biotechnology Statistics* publishes indicators on the number of biotechnology firms and R&D, employment and sales within these firms. Ideally, data on R&D, employment and sales are obtained for both biotechnology-related activities and for all activities of biotechnology firms. For example, many firms that perform biotechnology R&D also conduct R&D in other fields, or some sales could be due to non biotechnology goods and services. However, depending on the survey design, some studies are not able to provide results that are limited to biotechnology. Consequently, the OECD publishes data on all activities of biotechnology firms plus results that are limited to biotechnology. The only requirement is that each country includes metadata that clearly defines R&D, sales and employment data

Metadata Template for Business Surveys

Variable	Result	Comments
Reference year	______________	
Definition of biotechnology	☐ OECD definition ☐ Other 'modern' ☐ Other	*If 'other modern' or 'other', give details*
Definition of a biotechnology firm	☐ Core ☐ Bio-active ☐ Other	*If 'other', give details*
Must perform biotech R&D?	☐ Yes ☐ No	*Give details*
Sample frame	☐ Large scale survey ☐ R&D survey ☐ Secondary sources ☐ Other	
Number of firms surveyed	________	
Survey response rate	________%	
Results weighted?	☐ Yes ☐ No ☐ Not relevant	*If not relevant, give details*
Results extrapolated?	☐ Yes ☐ No Not relevant	*If not relevant, give details*
Coverage area	Describe if limited to a specific province, region, etc.	

Data Collection Template for the Biotechnology Activities of the Business Sector

Biotech firms

Country:
Reference year:

		Note (Please indicate whether the reference period differs; whether the indicator's comparability could be affected by your country's question wording or the population asked the question; details any reliability issues associated with the indicator, etc.	*Source* (name of survey, secondary sources, etc.)
Firms	1. Total number of biotechnology firms		
	2. Biotech firms by application field: Health Agro/Marine/Forestry Food & beverages processing Industrial Environmental Other: please specify Other: please specify	If not available please give approximate distribution by industrial sector	
	3. Total biotech firms by size-class: <50 employees 50-249 employees 250+employees		
R&D Firms	4. Expenditures on R&D by biotech firms (millions national currency) Total Of which: Biotech R&D		
Employment firms Sales firms	5. Employment in biotech firms Total employees Of which Biotech employees Total R&D employees 6. Total sales of biotech firms (millions national currency) Total sales Of which Sales of biotech goods & services	Please check if these data are for: Full-time equivalent (FTE)________ Headcount______	

plus the survey design or other information on how the data are obtained.

The template given below obtains the required metadata for the business sector, plus additional details are requested in the data collection template. The variables in column 1 are defined in section 4. The data collection template (available as an Excel file) defines six main indicators (if data are unavailable, the relevant cell should be left blank). Of note, wherever possible the OECD would like to have data on firm numbers disaggregated by the firm's main area of application for biotechnology. Five application areas are given, such as health (which includes both human and animal health), agriculture/marine/ forestry, food and beverage processing, industrial, and environmental. If data are not available at this level, applications can be combined. For example, the application 'industrial' could be combined with 'environmental'. The 'other' category can be used for different applications or for different ways of combining applications.

3. Methodology of Data Collection (metadata)

Due to the complexity of biotechnology, there are many different ways of defining biotechnology, a biotechnology firm, and of measuring biotechnology activities. For these reasons, *Biotechnology Statistics* includes information on the definitions used to collect biotechnology data as well as information on the methodology. Page 11 of *OECD Biotechnology Statistics 2006* summarises the necessary metadata for each country in a single table.

Business Sector

The following metadata are needed to support indicators of business sector biotechnology activities:

Year: Reference year for the biotechnology statistics.

Definition of Biotechnology: How biotechnology was defined, for instance in questionnaires sent to firms. Possible options include the OECD list based definition or other definitions of modern biotechnology.

Definition of a Biotechnology Firm: How a biotechnology firm is defined. For guidance, three defining characteristics are in common use:

Core biotechnology firm: The firm's main activity is biotechnology. Most of these firms are likely to be small, with less than 500 employees.

Most consulting reports, such as by Ernst and Young, are limited to core biotechnology firms.

Bio-active firm: Includes all firms with some activities in biotechnology. Some of these firms will be very large, with only a small share of total economic activities due to biotechnology.

R&D status of the firm: Both the definition of a core and a bio-active firm can vary depending on whether or not the firm performs biotechnology R&D. For example, R&D surveys capture all bio-active firms with some biotechnology R&D.

Definition of a Biotechnology Employee: All employees that have biotechnology-related responsibilities in R&D, production, administration, and management.

Sample Frame: Describe the basic structure of the sample frame. It is often difficult to construct a sampling frame for surveys of biotechnology firms because firms with some biotechnology activities can be difficult to identify. Three methods of constructing the frame are in common use:

Large Scale Survey: All firms are randomly sampled and asked if they have biotech activities. To save costs, these surveys are usually limited to sectors where biotechnology is thought to have applications.

R&D Survey: All respondents to the business R&D survey are asked if they have expenditures for biotechnology R&D.

Secondary Sources: A list of biotech firms is constructed from a diverse set of sources, such as biotechnology industry associations, searching patent data to identify firms that have applied for a biotechnology patent, results of previous R&D surveys, applicants to government support programmes for biotechnology R&D, etc.

Survey Response Rate: Give the percentage of the sampling frame that responded to the survey. In some cases this is not relevant, as when biotechnology data are extracted from the annual reports of firms.

Weighting and Extrapolation: Give details on weighting and extrapolation methods, if used. When the survey response rate is less than 100%, the results for non respondents can be extrapolated or imputed. When the survey is a random sample of a much larger population, the results should be weighted to reflect the full population. In both cases weighting and extrapolation techniques estimate indicators for the complete population of biotechnology firms.

Region: Give details if the survey is limited to a region or province of a country.

Public Biotechnology R&D Expenditures

The main challenge for indicators of public sector biotechnology activities is to determine if all government support or only a part of such support is adequately covered. The necessary metadata for government support of biotechnology R&D include the following:

Year: Reference year for the biotechnology statistics.

Definition of Biotechnology: How is biotechnology defined in support programmes for biotechnology R&D, etc.

Level of Government: Government R&D data can be limited to specific levels of government, such as federal expenditures only. Some information on this is necessary, particularly when different levels of government (federal, provincial/state, municipal) can fund biotechnology R&D.

Coverage: How was government R&D expenditure for biotechnology obtained? This can be based on surveying the location of the expenditures (for instance, universities and government research institutes) or on the source of the funding (different government ministries). The template on public biotechnology R&D uses the latter method.

Endnotes

[1] The report can be downloaded for free from http://www.oecd.org/dataoecd/51/59/36760212.pdf

[2] As an example, Biotechnology Statistics includes an output indicator for the total sales of biotechnology goods and services as a proxy measure of the economic effects of biotechnology. However, market sales data combine non-biotechnology inputs into the production of the good or service plus biotechnology inputs. The share of biotechnology inputs in the sales price is likely to vary substantially across applications, but less within applications.

[3] An earlier version of this template was produced in 2003 and circulated to OECD experts. Based on experience with the 2003 version, the complexity of the current template was reduced in order to focus on collecting useable data.

Bio Web

The **National Biological Information Infrastructure** (NBII) is a broad, collaborative programme to provide increased access to data and information on the nation's biological resources. The NBII links diverse, high-quality biological databases, information products, and analytical tools maintained by NBII partners and other contributors in government agencies, academic institutions, non-government organisations, and private industry.
http://www.nbii.gov/portal/server.pt

BIOTECanada is the national industry-funded association representing the broad spectrum of biotech constituents including emerging, established and related service companies in the health, agricultural, and industrial sectors. It is dedicated to the sustainable commercial development of biotechnology in Canada.

The year 2007 marks the 20th year of the national association dedicated to the promotion and awareness of biotechnology and its public policy issues. Incorporated in 1987 as the Industrial Biotechnology Association of Canada, it continues to serve as the voice for industry leadership to build a sustainable environment for the community of researchers and innovators.
http://www.biotech.ca/

Biotechnology Information Directory Section

The World Wide Web Virtual Library is available since 1995, as a public service of Cato Research. This directory contains over 3500 links to companies, research institutes, universities, sources of information and other directories specific to biotechnology, pharmaceutical development and related fields. It places emphasis on product development and the delivery of products and services.
http://www.cato.com/biotech/

BIO

In 1993, when there were but a handful of biotechnology drugs on the market and the sequencing of the human genome was projected for completion somewhere around 2005, two small Washington-based biotechnology trade organisations merged to create the Biotechnology Industry Organisation, better known as BIO. One of the founding organisations, the Industrial Biotechnology Association (IBA), primarily represented larger, established companies on Capitol Hill and before federal regulatory agencies; the other, the Association of Biotechnology Companies (ABC), represented emerging companies and universities, and focused on technology transfer issues, meetings and other business development activities.

BIO united the organisations' 503 companies and 18 employees under one umbrella with a representative governing board that reserved one-third of its seats for emerging companies. The goal was to achieve within the organisation a workable balance of power between the handful of large multibillion-dollar firms that launched the first wave of biotechnology products and the hundreds of startup and mid-size firms that were at the research and development stage.
http://www.bio.org/

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http://www.pjbpubs.com/pharmaceutical_biotechnology/index.htm
http://www.indianbiotechobserver.com/

Bio Stat

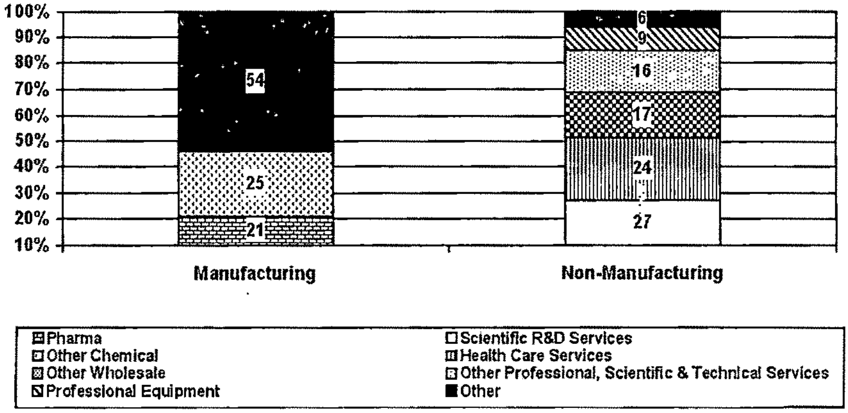
Biotechnology in the United States*

In 2003, 2,196 firms were undertaking biotechnology R&D, represented 6 per cent of all R&D-active firms. These firms spent PPP$ 14,232 million on biotechnology R&D, or 7 per cent of the total business enterprise R&D expenditures.

The majority of firms undertaking biotechnology R&D in 2003 were in the non-manufacturing sector and these constituted: 73 per cent or 1,609 firms. These firms were responsible for spending 62 per cent of all biotechnology R&D expenditures; the remainder was spent by the manufacturing sector.

The Scientific and R&D services sector in the non-manufacturing branch (North American Industry Classification System (NAICS) code 5417) had the highest share of biotechnology R&D expenditures: 36

US-based Firms undertaking Biotechnology R&D in the Business Enterprises Sector (NAICS), 2003



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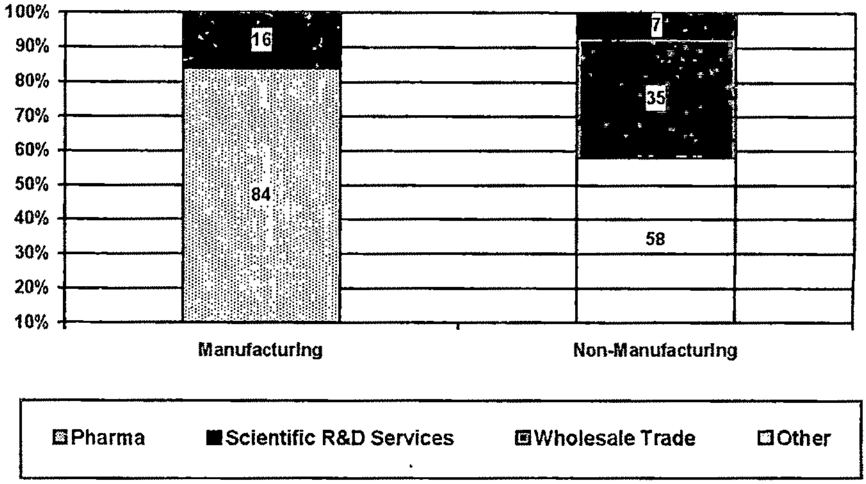
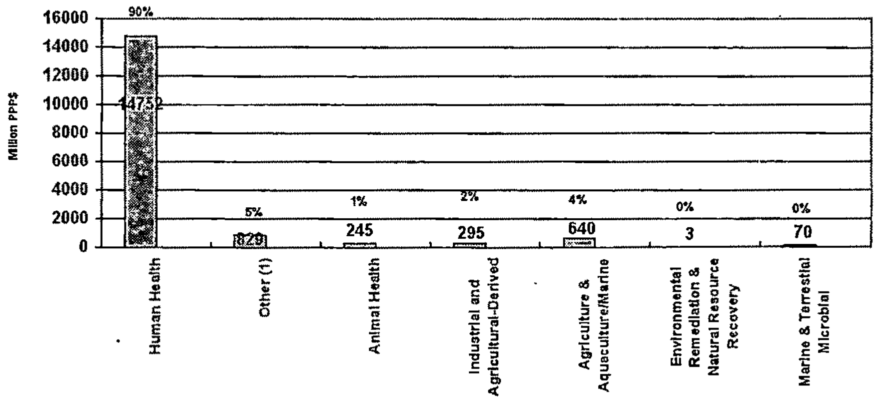
* Based on OECD (2006).

per cent of all biotechnology R&D expenditures. The Pharmaceuticals and Medicine sector in the manufacturing branch (NAICS code 3254) had the second largest share, with 32 per cent of total biotechnology R&D expenditures.

Ninety percent of the firms undertaking biotechnology R&D were Small and Medium-Sized Enterprises (SMEs) with fewer than 250 employees. However, these SMEs accounted for only PPP$ 3,614 million of biotechnology R&D, or 25 per cent of the total.



US Biotechnology R&D by application field, Million PPP$, 20001



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